

# Ghana

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## Preparing for the Management of Antiretroviral Drugs

Findings and  
Recommendations of  
the ARV Assessment  
Team

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Felix Yellu

April 2003



Ministry of Health /Ghana Health Service







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## DELIVER

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Ministry of Health /Ghana Health Service



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# Acronyms

AIDS	acquired immune deficiency syndrome
ANC	antenatal care
ART	antiretroviral therapy
ARVs	antiretroviral drugs
BI	Boehringer Ingelheim
CIDA	Canadian International Development Agency
CMS	Commercial Market Strategies
CRS	Catholic Relief Services
CSW	commercial sex worker
DOTS	directly observed treatment short-course
ELISA	enzyme linked immunosorbent assay
FHI	Family Health International
GAC	Ghana AIDS Commission
GAR Fund	Ghana AIDS Response Fund
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHS	Ghana Health Service
GMP	good manufacturing practices
HBC	home-based care
HIV	human immunodeficiency virus
IGF	Internally Generated Funds
IPPA	International Partnership Against AIDS in Africa
JSI	John Snow, Inc.
LMIS	logistics management information system
MOH	Ministry of Health
MSD	Merck, Sharp & Dome
MTCT	mother-to-child transmission
NACP	National AIDS Control Programme
NEDL	National Essential Drug List
NNRTI	non-nucleoside reverse transcriptase inhibitors
NVP	nevirapine
OI	opportunistic infection
PAI	Pharm Access International
PCR	polymerase chain reaction
PEP	post exposure prophylaxis
PHRL	Public Health Reference Laboratory
PLWHA	people living with HIV/AIDS
PMTCT	prevention of mother-to-child transmission
PPME	Policy, Planning, Monitoring and Evaluation
QA	quality assurance
RCH	Reproductive and Child Health Unit (GHS)
RH	reproductive health
RPR	rapid plasma reagin
RTD	rapid test devices
SSDM	Stores, Supplies and Drug Management Unit (GHS)

STG	standard treatment guidelines
STI	sexually transmitted infection
TB	tuberculosis
USAID	United States Agency for International Development
VCT	voluntary counseling and testing
VL	viral load
WAAF	West Africa AIDS Foundation
WHO	World Health Organization
WTO-TRIPS	World Trade Organization-Trade-Related Aspects of Intellectual Property Rights

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It is our sincere hope that the recommendations proposed in this report are implemented as swiftly as possible and that access to antiretroviral drugs for people living with AIDS in Ghana is soon a reality.

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# Executive Summary

The objectives of the assessment of the capacity to manage antiretroviral drugs in Ghana were to identify—

- strengths and limitations of the public sector antiretroviral therapy (ART) logistics systems
- current readiness to introduce and expand ART in selected Ministry of Health (MOH) sites
- policies and procedures needed to support service delivery and enhance logistics management of ART logistics
- strengths and limitations of the Central Medical Stores (CMS)/Pharm Access International (PAI) clinics logistics systems for distribution of ARV drugs.

It will also provide recommendations for strengthening the system capacity.

Four tools were designed and used by JSI/DELIVER and Ghanaian counterparts:

1. Central Level Questionnaire
2. Facility Logistics Management Questionnaire
3. Facility Service and Infrastructure Questionnaire
4. Tool to Assess Site Program Readiness for Initiating Antiretroviral Therapy

Eighty people from public and private sector organizations were interviewed. Sites visited were preparing to or already implementing ART, designated for ART initiation, already using ARVs for PMTCT, and/or selected as CMS/PAI ART initiative sites.

The following were the major findings:

## A. *Strengths*

- Responsibility for national response has been established.
- Protocols and guidelines have been established for key intervention areas in HIV/AIDS.
- Short term to medium term financing for ARVs and HIV-related commodities has been secured.
- A systematic planned process for ART implementation has been adopted.
- Some private health facilities are eager, ready, or have initiated ART.
- Good laboratory support infrastructure exists.
- Laboratory capacity is adequate to provide initial support to ART in sites visited.
- Pharmacy management is adequate to support ART in Ghana.

### B. *Limitations*

- Clear policy and framework for cost of ART to patients is not yet determined.
- Leader for the National ART Program has not been designated.
- Logistics management information system (LMIS) is either weak or nonexistent for certain HIV/AIDS products.
- Poor coordination between various implementers and stakeholders.
- HIV/AIDS commodity forecasting is weak.
- Selection of ARVs is incomplete.
- Private sector use of ARVs is poorly regulated.

The primary recommendations resulting from this assessment are listed below. A full discussion of each recommendation can be found in the section on Conclusions and Recommendations.

## Logistics Management

1. National AIDS Control Program (NACP) needs to appoint and seek assistance to train an HIV/AIDS logistics manager to be responsible for coordinating commodity forecasting, procurement and distribution of HIV/AIDS-related commodities; working in conjunction with all stakeholders, including private sector providers and funders.
2. NACP should seek assistance to design and implement a LMIS to capture essential logistics data and track product use in the system. Standard formats should also be instituted for the reporting of service information.
3. The MOH should develop a strategic approach to ensure the medium term to long term security of a supply source for ARVs.
4. NACP and the Procurement and Supplies Division should establish an HIV/AIDS Commodity Coordination Group to coordinate and improve methodologies for forecasting ARVs, HIV tests, and other HIV/AIDS-related commodity requirements; and to monitor the supply status of these commodities. This group should include all stakeholders involved in the provision of ART, including Government of Ghana entities, private sector providers, and funders.
5. All HIV/AIDS commodities should be procured and managed by the MOH. The Ministry of Health should foster public-private sector partnerships to ensure effective procurement and distribution of HIV/AIDS commodities. The existing MOH procurement, storage and distribution systems and alternative management systems should be reviewed. Weaknesses in the current systems should be addressed to ensure accountability and security for all health commodities to the satisfaction of all stakeholders.
6. NACP and the Procurement and Supplies Division should develop interim procedures for management of ARVs, including procedures for issuing to service sites and a system for monitoring facility stock levels of ARVs. They should also develop a plan for the long-term management of ARVs.

7. NACP should coordinate the supply of ARVs and the provisions of ART in both the public and private sector, with the possibility of a common supply source for HIV/AIDS-related commodities. The MOH should foster public-private sector partnerships in providing of ART to ensure wider access for those in need of treatment.
8. Ghana AIDS Commission and NACP should identify a set of logistics system performance indicators to monitor the implementation of the ART supply system.

## **Policy, Program, and Service**

1. The MOH should determine what the cost of ART will be to the patient and take the necessary policy actions.
2. The AIDS Control Program (ACP) needs to appoint an Antiretroviral Therapy Coordinator to ensure the rational and effective introduction of ARVs in the public sector, to monitor ART in the private sector, and to solidify the technical leadership of NACP in this area.
3. The Ministry of Health/Ghana Health Service should take steps to incorporate the Guidelines for Antiretroviral Therapy in the National Standard Treatment Guidelines.
4. NACP should work with the Food and Drugs Board and the Pharmacy Council to establish a mechanism for monitoring and regulating the ARVs that are available through commercial pharmaceutical companies.
5. The MOH should take the necessary steps to include HIV/AIDS commodities on the *National Essential Drug List* (NEDL).
6. When selecting sites to begin ART, NACP and the MOH should base the selection on the site's readiness to implement HIV/AIDS care and the extent of preparations needed.
7. NACP and the administration of each ART program site should identify and appoint an ART manager at each site to monitor quality and performance of the ART program during the introduction and implementation of ART services.



# Background

## HIV/AIDS Prevalence and Impact

The first AIDS cases were diagnosed in Ghana in 1986. Current estimates are that 3.6 percent of the population is infected with HIV, with the majority being in the 15 to 49 age group. The prevalence rate has been steadily rising from 2.7 percent in 1994 to 3 percent in 2001 to the current rate of 3.6 percent. The National AIDS Control Programme (NACP) projects the prevalence rate of HIV/AIDS to increase to 4.7 percent by 2004, 6.9 percent by 2009, and 9.0 percent by the year 2014, in a worse case scenario, and to 4 percent if preventive efforts are intensified. Heterosexual transmission accounts for 75–80 percent of infection with mother-to-child transmission (MTCT) accounting for 15 percent, while parenteral transmission accounts for 5 percent.

By the end of December 2000, a cumulative total of 43,587 AIDS cases had been recorded, 90 percent between the ages of 15–49 years, with 63 percent of all reported HIV/AIDS cases being women. While the rise in the prevalence rate has not been as dramatic as in other African countries, the continued increase is of great concern. Deaths from AIDS-related causes are predicted to account for 28 percent of deaths by the year 2014. If not addressed, increased morbidity and mortality due to AIDS will not only stretch the capacity of health care services, but will also adversely affect the economic productivity of the nation.

## Government of Ghana's Response to HIV/AIDS

Soon after the identification of HIV/AIDS in Ghana, the Government of Ghana responded by establishing the NACP in 1987 to coordinate the national response to the epidemic. Several short- and medium-term plans for prevention and control have been developed by the NACP, and have guided activities from 1987 to the present. Over time, other governmental, nongovernmental, and private organizations have become involved in HIV prevention activities. In 1997, the Policy Document in HIV/AIDS was spearheaded by the NACP. The objectives of the policy focused on—

- Reducing morbidity and mortality due to HIV/AIDS.
- Protecting the human rights of people living with AIDS (PLWHA) and ensuring access to care and economic opportunities.
- Promoting information and education about HIV/AIDS.
- Minimizing the socio-economic impact of the epidemic.

Recognizing that the HIV/AIDS situation in Ghana requires a multi-sectoral approach, the Government of Ghana created the Ghana AIDS Commission, which was inaugurated in September 2000. The Commission is the highest policy making body on HIV/AIDS. A supra-ministerial and multi-sectoral body, the Commission serves under the Office of the President. The role of the Commission is to direct and coordinate all activities in the fight against HIV/AIDS.

The Commission has put forth the National Strategic Framework (2001) with the following objectives for HIV/AIDS activities:

- To reduce the current prevalence rate by 30 percent by 2005.
- To create an enabling environment for PLWHAs.
- To improve service delivery and mitigate impact of HIV/AIDS on individuals and families.
- To establish a multi-sectoral and multi-disciplinary institutional framework for coordinating and implementing HIV/AIDS programmes in Ghana.

The strategies for implementation of the framework include awareness creation; support and care for PLWHAs; voluntary counseling and testing; treatment and care; and research, monitoring, and evaluation. The Commission receives support through the Ghana AIDS Response Fund (GAR Fund) and, in turn, provides support to a wide range of community, faith-based, and other nongovernmental organizations, and governmental units at the local and national level.

The Health Sector HIV/AIDS Strategic Plan 2002–2006 (dated October 2002) provides the general principles and aims for HIV/AIDS activities of the MOH:

- To increase access to quality HIV/AIDS/sexually transmitted infection (STI) prevention and care services to all clients through strengthening the technical and operational capacity of the MOH and other stakeholders to deliver quality HIV/AIDS and related services.
- To reduce employees vulnerability and susceptibility to HIV and AIDS by establishing a workplace HIV/AIDS program for all health workers.
- To strengthen the collaboration between the MOH and other sectors and to provide technical support to other sectors and stakeholders involved in HIV/AIDS.
- To create an enabling policy environment for the HIV/AIDS response within the health sector.

Activities to initiate and support the provision of antiretroviral therapy are clearly in line with the first objective of the HIV/AIDS Strategic Plan and are explicitly stated in specific objective B5 and included in the package of interventions.

*Objective B.5.*

“To identify and implement the optimal ways to provide antiretroviral therapy (ART) to PLWHA in equitable, appropriate, safe and sustainable ways.”

The goal of the strategic plan related to antiretroviral therapy (ART) is to have antiretroviral (ARV) drugs available in targeted centers by 2003, with a target of 6,000 PLWHAs receiving ART annually. The plan also calls for the effective management of all drugs for HIV/AIDS activities at the national, regional, district, and health facility level.

To support ART activities and other activities in HIV, the MOH submitted a successful proposal to the Global Fund to Fight AIDS, TB and Malaria (GFATM). In addition to support for capacity building and other activities, GFATM funds will be used to purchase ARVs, HIV tests, and other commodities needed to provide comprehensive HIV/AIDS prevention, treatment, and care services.

## Antiretroviral Therapy in Ghana

### Public Sector

Realizing that in order to alleviate the impact of AIDS on families and communities, the Government of Ghana is committed to an expanded program of care and support including the provision of medical care needed by people living with HIV/AIDS.

The Family Health International (FHI) Start Program, in collaboration with the Government of Ghana, and funded by FHI and USAID, has established comprehensive HIV/AIDS clinical and community-based prevention, care and treatment services in the Atua Government Hospital and St. Martin's Catholic Hospital for the Manya Krobo and Yilo Krobo Districts of the Eastern Region. These two facilities will be the first facilities to provide ART in Ghana. ART is scheduled to start in these facilities by May 2003. By the end of 2003, the MOH is planning to expand ART services to Korle Bu Teaching Hospital in Accra and Komfo Anokye Teaching Hospital in Kumasi. The goal is to provide ART to 2000 patients by the end of 2003, with an ultimate goal of treating 6,000 patients.

Several efforts are being made to ensure availability of drugs for the management of opportunistic infections (OI), as well as antiretroviral drugs. Some specific initiatives include the following:

- Development of guidelines on the management of OIs.
- Development of guidelines on ART.
- Training-of-trainers in the use of these guidelines.
- Setting up of VCT sites for testing as entry point to care.
- Negotiations for price reductions in ARVs. CIPLA, an Indian pharmaceutical company manufacturing generic drugs, has made an offer that will cost U.S.\$350 per year per adult for a triple drug combination.
- Signing of a Memorandum of Understanding with Merck, Sharp & Dome for possible purchase of efavirenz and indinavir at reduced prices.
- Discussions on local manufacture of ARVs in collaboration with WHO and the Thai Government, the latter for technology transfer.
- Grant from Global Fund for treatment of 2,000 PLWHAs in the next two years.

ARV drug requirements, as captured in the Health Sector HIV/AIDS Plan, estimates a target group of 6,000 persons. The estimates were based on the reported cases for the year 2000 and also on the eligibility criteria in the treatment guidelines. Drugs for prevention of MTCT are already programmed for free supply under an arrangement with Boehringer Ingelheim, a South African subsidiary of a German Pharmaceutical Company.

### Private Sector

Pharm Access International (PAI), with support of the Royal Netherlands Embassy, and the USAID-funded Commercial Market Strategies (CMS) are assisting private sector treatment facilities to initiate ART, and to promote the use of such facilities by private employers. Three private health care facilities in Accra have been identified for this initiative: Akai House Clinic, Nyaho Clinic, and Holy

Trinity Hospital. Negotiations are also underway with Ashanti Goldfields and Unilever about the possibility of supporting ART treatment at their corporate medical facilities.

PAI will provide clinical training for physicians and technical assistance to the facilities, including medical and laboratory consultation and quality monitoring. PAI will also be working with Medlab to develop the capacity to do CD4 and viral load tests, and assist in the development of laboratories at the other sites, depending on the ability of these facilities to invest in the necessary equipment. CMS will arrange training for counselors and work to inform Ghanaian employers of the availability and cost of the ART service, and to assist interested companies in developing policies that will facilitate the provision of this service. Drugs sufficient for first-line ART are registered in Ghana and are being imported at prices that should permit retail purchase of triple therapy for \$3 a day or a bit more. At least four Cipla products and Combivir® of GSK are being imported on this basis.

Twenty antiretroviral drug preparations are registered in Ghana and several local drug wholesalers have begun importing ARVs into the country. As a result, ARVs are now available in commercial pharmacies. At this point, prescriptions of ARVs are not regulated and the opportunity for misuse is a real threat to individual and public health. A list of the ARVs registered in Ghana at the time of this report is included in the annex.

### **Support for HIV/AIDS Activities in Ghana**

NACP is responsible for providing technical support for HIV/AIDS activities in Ghana. The Ghana AIDS Commission provides policy support and coordinates the multi-sectoral response to HIV/AIDS. In addition, numerous international organizations work in collaboration with NACP and the Commission, and offer a wealth of experience and assistance.

FHI, funded by USAID, provides technical assistance in the development of comprehensive HIV/AIDS prevention, treatment, and care, and is responsible for guiding the initiation of ART in Ghana. USAID provides technical assistance in logistics, social marketing, private sector initiatives, and limited direct support for procurement of ARVs. WHO and the European Union (EU), among other activities, have supported prevention of mother-to-child transmission (PMTCT) services. The World Bank provides financial support for the MOH and Ghana AIDS Commission activities, and is a major funder of the GAR Fund. UNAIDS provides technical guidance and donor coordination. Other donors and groups involved in HIV/AIDS activities include DANIDA, DFID, UNFPA, UNICEF, UNDP, CARE International, World Education, Royal Netherlands Embassy, JICA, and numerous others.

# Assessment Framework and Methodology

## Purpose and Objectives

The overall purpose of the assessment was to assist the MOH/Ghana Health Services (GHS) in identifying the logistical and clinical issues that need to be addressed to support the initiation and expansion of ART services in the country. The assessment focused on two areas: logistical requirements for ensuring a reliable and consistent supply of quality ARVs, and infrastructure and personnel requirements necessary to ensure their safe and effective use by patients. The assessment findings and recommendations will be used by the MOH in furthering the development, implementation, and expansion of the national ART program through the establishment of an efficient and effective logistics management system to support antiretroviral treatment services, including antiretrovirals (ARVs), HIV tests, and related laboratory commodities. Additionally, the assessment looked at ART services provided in the private sector that are supported by CMS/Pharm Access International.

The specific objectives of the assessment were to—

- Identify strengths and limitations of the current MOH logistics system for procurement, storage, and distribution of ARV drugs; and provide recommendations for strengthening the system capacity.
- Document/identify the current readiness in terms of personnel and infrastructure to introduce and expand ART in selected MOH sites.
- Identify the MOH policies and procedures needed to support service delivery and to enhance logistics management of ART drugs and related laboratory supplies.
- Identify strengths and limitations of the CMS/Pharm Access International clinics logistics system for procurement, storage, and distribution of ARV drugs, and to provide recommendations for strengthening the system capacity.

## Assessment Framework

The assessment looked at elements of commodity security at the national level and at all the key functions of the logistics system required for the ART program at the facility level. Specifically, at the national level, the assessment focused on—

- policy and oversight
- forecasting
- financing
- procurement and quality assurance
- distribution.

At the facility level, the assessment focused on the following elements of the logistics cycle for health commodity management:

- service, including continuum of care and laboratory/pharmacy capacity
- product selection
- inventory management
- storage
- dispensing
- logistics management information systems.

The logistics system ensures that the right quantities of quality products reach the right places at the right time. Products for the ART program need to be selected first and registered for use. Then, during the initiation and expansion stages of ART, drug requirements are quantified for the short-term (one–three years) and their use is closely monitored. Forecasts should be routinely updated and procurement plans adjusted accordingly. The products must then be procured, cleared through customs, and undergo quality control checks. After the program's logistics system, inventory management, and distribution, which includes transport and storage at perhaps several levels, must be carefully coordinated so that the products reach the service delivery points where they can be used. This process must be supported by an effective policy and legal framework, consisting of operational procedures, regulatory authority for quality assurance, and efficient registration processes that allows new products to be registered quickly for import.

As figure 1 shows, ART is part of a continuum of care in a comprehensive approach to HIV/AIDS that includes prevention, diagnosis, treatment of opportunistic infections (OIs), palliative care, antiretroviral therapy for AIDS, and psychosocial support services. Management of ART services should be linked with other existing HIV/AIDS prevention and care activities and service delivery systems.

The organization and operations of a service delivery program are crucial for the design and functioning of a logistics system. The logistics system must respond to and support the policies, regulations, protocols, and guidelines that govern delivery of services. Figure 1 depicts the broad spectrum of commodities needed to support a comprehensive HIV/AIDS program. More than 120 different health commodities are required to provide the full range of prevention, diagnostic, and treatment services. Laboratory services for screening and monitoring must also be available at different levels of care and a multi-disciplinary pool of human resources must exist for effective delivery of services. Successful procurement, distribution, and use of HIV/AIDS commodities depends on the support of an established laboratory infrastructure and capacity; a well-functioning supply chain to ensure uninterrupted delivery of product; and provider, client, and community education and involvement in implementing these services.

HIV/AIDS programs are complex, and logistics management of some HIV/AIDS products is particularly challenging. Examples of logistics issues include the following.

- A reliable and uninterrupted supply of ARV drugs is absolutely critical given that more than 90–95 percent adherence to ART is required for the regimens to be effective over the long term. In a twice-a-day regimen, this means that less than one dose every two weeks can be missed. Lower levels of adherence are associated with development of drug-resistant HIV.

- Strict monitoring of inventory levels and secure storage facilities are needed because of the high price of ARVs and other HIV/AIDS commodities. Their use for prolonging survival and improving quality of life makes them highly subject to pilferage and leakage to other markets.
- Combinations of at least three drugs are required for highly active ARTs, and maintaining equal stock levels of different combinations of drugs will be challenging for service providers. Appropriate inventory control systems are needed to maintain a full (rather than rationed) supply of ARVs for each level of the system.
- PMTCT programs in resource-limited settings use either one drug (AZT or nevirapine) or two drugs (AZT plus 3TC). Even this short course carries a risk of developing ARV drug resistance, which would decrease the efficacy of subsequent ARV regimens. Product selection for ART needs to take into consideration drug selection for PMTCT.

**Figure 1.**  
*Commodities for a Comprehensive HIV/AIDS Program*

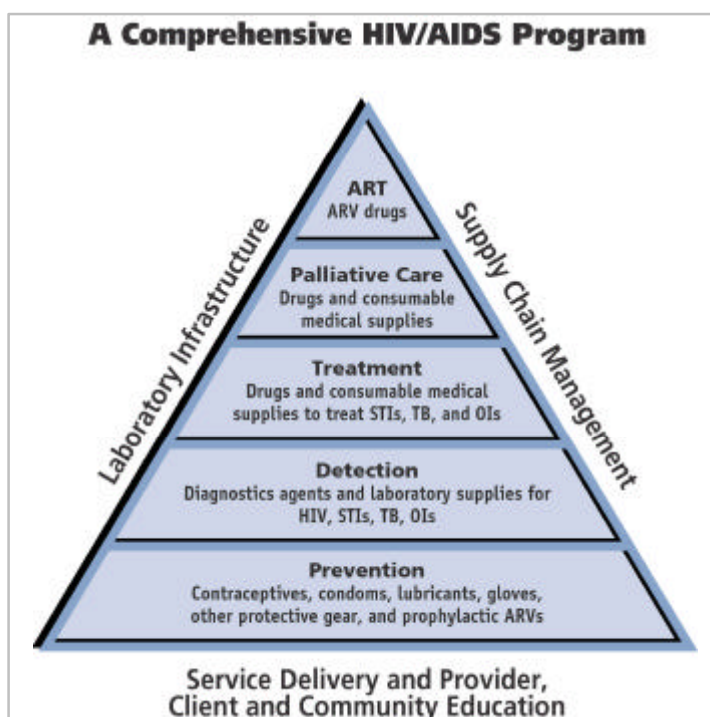


Figure 2 shows the steps and services that must be available to identify, enroll, and monitor patients in an ART program. Commodities are required at each stage of a patient's care. The team assessed the capability of the selected sites and wider health system to organize and deliver these ART services by looking at their existing services for testing and treatment of tuberculosis (TB), OIs, and STIs. The experience and lessons learned in providing these services will be crucial to the introduction and expansion of a national ART program.

Figure 2 also emphasizes that, for an ART program, logistics management of ARVs does not end with delivery of the drugs to the pharmacy, but rather ends when the drugs are prescribed properly and dispensed correctly by providers and taken as directed by patients. The logistics requirements for

an ART program are unique because they must ensure safe and effective lifelong use of the medications. In resource-limited settings, this is a complex challenge.

**Figure 2.**  
*ART Implementation Framework*



## Methodology

### Assessment Team

The three-week assessment was conducted from April 7–25, 2003, by an eight-member team that included three JSI/DELIVER staff, two FHI/Ghana staff, and three MOH/GHS staff. The team included four clinicians (one trained and experienced in logistics), three pharmacists (one trained and experienced in logistics), and a logistics specialist. Teams for site assessments and key informant interviews were purposely composed to include a clinician, a pharmacist, and a logistician.

### Tools

Four tools, developed by DELIVER, were used to gather and analyze information for the assessment. Copies of the tools are included in the annex to this report.

The *Central Level Questionnaire* provided an interview guide for discussions with policy and program staff. The questionnaire deals with policies on service provision (VCT, PMTCT, post exposure prophylaxis [PEP], ART, and laboratory support) and support to ART programs (financing, personnel capacity and training, community involvement, research, and procurement planning).

The *Facility Logistics Management Questionnaire* was administered at the eight service facilities visited. The tool covers all logistics aspects of how facilities are currently managing several HIV/AIDS related products: availability, security measures, ordering, storage, quality control, transport, and logistics recording and reporting. HIV/AIDS-related products were used as a *proxy* for ARVs, because ARV use is currently very limited. Products covered included HIV test kits, drugs for treating OIs (e.g., fluconazole, cotrimoxazole), TB drugs (rifampicin, ethambutol), STI drugs (e.g., doxycycline, metronidazole), ARVs (nevirapine), and laboratory test supplies (pipettes).

The *Facility Services and Infrastructure Questionnaire* is an interview guide for discussions about HIV/AIDS-related services with personnel at the public and private health facilities. The services covered include VCT, PMTCT, home-based care (for HIV-related illnesses), management of OIs and STIs, TB diagnosis and treatment, and ART, where already initiated. Information was collected on each available service: frequency of service, staffing, training, use of partner organizations, use of protocols, patient load in previous month, and record keeping.

After conducting the assessment using the three tools discussed above, team members used the *Tool to Assess Site Program Readiness for Initiating Antiretroviral Therapy (ART)* to provide an overall assessment of the readiness of a particular site to provide ART. The goal of rating the Stages of Readiness is to develop a set of criteria for selecting ART sites not based on site type, but on capacity, vision, and activities needed for rational introduction and expansion of ART into HIV care. Six domains of a program were reviewed to assess site readiness: Leadership; Services; Protocols, Management, and Evaluation; Experience and Staffing; Lab Capacities; and, Drug Management and Procurement. Based on domain scores, sites are rated on their stage of readiness. The evaluation of each of these domains determine into which of the five stages a program falls. The stages rating system can be used for program start-up and expansion within the site to identify steps needed to advance a site along the stages from a *Program Mobilization* stage (Stage 1) to an *Action* rating (Stage 4) and, ultimately, *Support, Maintenance, and Expansion* (Stage 5). At the end of the tool, examples of technical assistance, training, and resources that may be needed to advance a site to a higher stage are suggested for each rating.

### Interviews

Approximately 80 people from 25 public and private sector organizations were interviewed as part of the assessment, which included visits to four public sector health facilities and four private sector facilities. The people interviewed included HIV/AIDS program managers, researchers and clinicians, pharmaceutical experts, procurement specialists, warehouse managers, nongovernmental organizations (NGOs) involved in community services, directors, and health officers of donor organizations. Table 1 lists the organizations contacted. The annex includes a list of all persons contacted.

**Table 1. Organizations Contacted for Assessment, April 2003**

<b>Public Health Sector Organizations</b>	<b>Health Facilities</b>	<b>Donors and Collaborating Agencies</b>
Ghana AIDS Commission	St. Martin's Catholic Hospital	USAID
CCM/MOH	Atua Government Hospital	Family Health International/Accra
Health Research Unit/MOH	Korle Bu Teaching Hospital	World Bank
SSDM/GHS	Komfo Anokye Teaching Hospital	Commercial Market Strategies/Accra
NACP	Akai House Clinic	UNAIDS
Food and Drug Board	Nyaho Clinic	
National Public Health Reference Laboratory/GHS	Holy Trinity Hospital	
Noguchi Memorial Institute for Medical Research	Ashanti Goldfields Hospital	
PPME/MOH	Medlab	
PPME/GHS		
Reproductive Health Unit, GHS		

***Health Facilities Selected***

The team visited four public sector and four private health facilities to obtain information about their HIV/AIDS-related services and logistics management systems. The sites selected were currently doing *one or more* of the following (not all activities are listed):

- Currently using ARVs for ART.
- Currently using ARVs for PMTCT only.
- Actively preparing to introduce ARVs for ART.
- Designated by the draft national plan as an ART initiation site.

# Findings

## I. National Level

### Policy and Oversight

Ghana, like many other countries, initially considered HIV/AIDS as a health problem and, therefore, focused the national response on the health sector. A joint review of the national response by a team from the government, UNDP, USAID, and other development partners recommended the establishment of a National Advisory/Coordinating Body to advise the government on the HIV/AIDS policy and other related issues. A follow-on review in 1999 by the International Partnership Against AIDS in Africa (IPAA) also advocated for the establishment of a supra-ministerial body to advise and coordinate all HIV/AIDS related activities. The implementation of these recommendations saw the establishment of the Ghana AIDS Commission (GAC) in May 2000. The Commission is a 46-member body, with 15 members representing various Ministries, including either the Minister or the Deputy Minister. Other members include representatives of Civil Society organizations, faith-based organizations, the private sector, and people living with HIV/AIDS. The Commission is chaired by His Excellency, the President of the Republic of Ghana. The main objectives of the commission are—

- To formulate comprehensive national policies and strategies and establish program priorities relating to HIV/AIDS.
- To provide high-level advocacy for HIV/AIDS prevention and control.
- To provide effective leadership in national planning and coordination of support services.
- To expand and coordinate the total national response to HIV/AIDS.
- To mobilize, control, and manage resources and monitor their allocation and utilization.
- To foster linkages among all stakeholders.
- To promote research, information, and documentation on HIV/AIDS.
- To monitor and evaluate all on-going HIV/AIDS activities.<sup>1</sup>

The government's policy of decentralization constitutes a key principle underlying the GAC's approach to the planning and implementation of HIV/AIDS activities. The GAC works through seven committees: Steering Committee, Project Review and Appraisal Committee, Legal and Ethical Committee, Prevention and Advocacy Committee, Care and Support Committee, Resource Mobilization Committee, and the Research, Monitoring and Evaluation Committee.

The GAC published a five-year strategic framework for the period 2001–2005 to guide the national response. The comprehensive strategic framework document developed through a consultative process was completed in June 2001.

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<sup>1</sup> Ghana AIDS Commission, Annual Report for the year ended December 31, 2001.

The strategic framework is based on the five guiding principles:

- a multi-sectoral partnership approach
- respect for fundamental human rights
- access to information and comprehensive services
- decentralization, community participation, and individual responsibility in all HIV/AIDS programs
- adequate resource (financial and human) mobilization to implement the framework.<sup>2</sup>

The strategic framework identified five thematic or intervention areas along which programs will be developed:

- prevention of new transmission of HIV
- care and support for PLWHA
- creating an enabling environment for national response
- decentralized implementation and institutional arrangements
- research, monitoring, and evaluation.

These interventions have the following objectives:

- To reduce new HIV infections among the 15–49 age group and other vulnerable groups, especially the youth, by 30 percent by 2005.
- To improve service delivery and mitigate the impact of HIV/AIDS on individuals, the family, and the communities by 2005.
- To reduce individual and social vulnerability and susceptibility to HIV/AIDS by creating an enabling environment for the implementation of the national response.
- To establish a well-managed multi-sectoral and multi-disciplinary institutional framework for coordinating and implementing HIV/AIDS programs in the country.

The broad strategies in the area of care and support include—

- Promoting voluntary counseling and testing of individuals, especially the youth.
- Improving institutional care, including access to drugs for PLWHA.
- Promoting community and social care and support, including home-based care.
- Promoting effective linkages between institutional and home-based care provider.

The Ministry of Health/Ghana Health Service is responsible for the institutional care of HIV/AIDS patients, and the main unit of implementation of its activities is the NACP. The MOH established the NACP in 1987.

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<sup>2</sup> Ghana HIV/AIDS Strategic Framework 2001–2005, Ghana AIDS Commission.

The MOH has a new draft HIV/AIDS Strategic Plan 2002–2006.<sup>3</sup> When finalized, this will guide all HIV/AIDS-related programming under the current five-year medium term health strategy, which spans the same period.

The package of interventions under this strategic plan is summarized below:

- prevention of new transmission
- health promotion and demand creation
- voluntary counseling and testing
- STI management
- ensuring blood safety
- HIV exposure prevention in health care settings
- HIV exposure prevention in settings outside the health sector
- prevention of mother-to-child transmission
- condom promotion.

Care of PLWHA:

- continuous supportive counseling
- prevention and management of OIs
- antiretroviral therapy.

## Monitoring and Evaluation

The need for a clear monitoring and evaluation plan in the implementation of such a diverse and far reaching range of programs, such as those in the HIV/AIDS area, cannot be disputed. The existing monitoring and evaluation plans, and the selected indicators of performance, are related to the funding sources from which the related activities will be implemented, and they are presented below by funding source:

### ***Global Fund M&E***

Three main objectives related to the use of antiretroviral drugs can be identified under the Global Fund-related activities as presented in Ghana's proposal to the fund:

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<sup>3</sup> HIV/AIDS Strategic Plan 2002–2006, Ministry of Health, October 2002, Reviewed April 2003.

**Objective 1: To increase voluntary counseling and testing service points from 4 to 24 points in the country with at least one point in each region by December 2003<sup>4</sup>**

Indicators	Baseline %	Targets %				
	2001	2002	2003	2004	2005	2006
Percentage of 24 planned VCT centers established	18	40	60	100	100	100
Percentage of established VCT sites patronized by at least 20% of persons between the 12 and 49 years age group		40	60	90	90	90
Percentage of the 24 VCT centers with at least 3 trained counselors		40	80	100	100	100
Percentage of VCT centers with good linkage to efficient laboratory services		40	80	90	90	90

**Objective 2: To expand PMTCT pilot programme from 2 sites to 24 sites by December 2003, with at least one site in each region**

Indicators	Baseline %	Targets %				
	2001	2002	2003	2004	2005	2006
Percentage of 24 planned sites which are operational	8.3	40	90	100	100	100
Percentage of 24 sites with enough adequately trained staff		40	90	90	90	90
Percentage of sites with constant supply of required drugs and supplies		40	90	100	100	100

**Objective 3: To establish and make operational at least 3 centers providing comprehensive care including OI management and ART for PLWHA by December 2003**

Indicators	Baseline %	Targets %				
	2001	2002	2003	2004	2005	2006
Percentage of centers established		33	100	100	100	100
Percentage of centers with trained personnel		33	100	100	100	100
Percentage centers with constant adequate supplies and drugs			100	100	100	100
Percentage of PLWHA receiving ARTs		40	50	60	70	70
Percentage of persons able to tolerate ARV						
Percentage of persons adhering to drug regime		40	80	90	90	100

<sup>4</sup> Ghana Global Fund Proposal. March 2002.

### ***Ghana AIDS Commission***

The Ghana AIDS Commission has developed a draft Monitoring and Evaluation Framework.<sup>5</sup> The monitoring framework identifies outcome indicators for assessing the various intervention areas. Two indicators related to the use of ARVs are listed below.

- Number of sites providing PMTCT services.
- Percentage of HIV infected pregnant women receiving a complete course of ART prophylaxis to reduce the risk of MTCT.

While the above describes the monitoring of detailed implementation plans, most of these plans have yet to be implemented. Some examples of activities still to be implemented are discussed below:

- There are currently only two VCT sites in the country, which are the FHI-supported pilot sites in Manya Krobo District.
- Counseling for HIV/AIDS testing is quite widespread in both public and private sector testing sites, but is not provided within the framework of established standards of care. The National AIDS Control Program has produced draft VCT guidelines, but these have not been formalized and disseminated.
- Development and setting of standards for accreditation of VCT providers has not been done. Creation of standards would guide public and private sector providers, and providers of workplace intervention programs outside the health sector, in establishing appropriate VCT services.
- Guidelines for conducting HIV tests are addressed in the draft HIV/AIDS and STI Policy. However, this document is not finalized. It has also been stated that there should be no laboratory testing without prior counseling; however, this has not been enforced.

There are some gaps in program oversight and monitoring and evaluation of the national response, especially on the use of ART drugs. Currently, there are no clear program plans for coordination and monitoring of the use of ART drugs in the private sector. The lack of any formal or informal reporting arrangements between the private-sector health delivery system and the MOH creates a situation for concern. Private providers are not necessarily motivated to report patient statistics or related data to the MOH.

A similar situation exists in the retail pharmaceutical sector. There is currently no requirement that data on the distribution of ARVs be reported to any central unit. There are emerging concerns that some ARVs are available in the private sector to patients who can afford to pay commercial rates. While the veracity of this situation and its true extent could not be ascertained as part of this assessment, the existence of such a pattern in the use of ARVs should be of concern.

Unfamiliarity about the use of ARVs among health professionals suggests that their uncontrolled availability through commercial outlets needs to be closely monitored.

Of similar concern was the discovery that an Accra-based NGO, West Africa AIDS Foundation (WAAF) is currently treating HIV/AIDS patients at its hospice in Accra, and has plans to expand its services to other parts of the country in the near future. It is not clear if any particular or consistent treatment protocol for ART has been established. The hospice mentioned an arrangement by which

<sup>5</sup> 8<sup>th</sup> Draft National Monitoring and Evaluation Framework for HIV/AIDS, Ghana AIDS Commission. February 2003.

drugs are recycled (donated) from the USA for use at the clinic. It was not possible to establish if the commodities donated to this facility are the same as those recommended in the national treatment protocols. Another area of concern about the activities of this facility is the fact that it claims to have been registered by the Food & Drugs Board to import ARVs for research purposes.

Another important finding on the general oversight of the program is the fact that the current NEDL, last reviewed in 2000, does not include the ARV drugs required to provide ART according to the established first- and second-line treatment regimens. Only one product for ART is currently on the NEDL.

### Forecasting

Forecasting of commodity requirements to support HIV/AIDS activities in Ghana is currently based on targets set for service delivery and established treatment and testing protocols. More accurate consumption-based forecasts will only be possible if essential logistics data on commodities dispensed to clients is collected on a routine basis. In addition, service-based forecasts can be refined as information about program acceptance and severe adverse reactions to ARVs becomes available.

#### ***HIV Tests for Voluntary Counseling and Treatment***

The forecast of HIV tests required for VCT are prepared by the Public Health Reference Laboratory based on the target of testing 2,000 clients in each VCT center each year. There are currently two VCT centers in full operation in Manya Krobo at the Start Program sites, Atua Government Hospital and St. Martin's Catholic Hospital. It is anticipated that two additional sites will provide VCT by the end of 2003 and, by the end of 2004, a total of 24 VCT sites will be established.

Based on facility reports, in the eight-month period between July 2002 and February 2003, St. Martin's Catholic Hospital tested 954 VCT acceptors, an average of 120 tested in a month. Atua Government Hospital tested 495 VCT acceptors in the six-month period between July and December 2002, or an average of 83 tested in a month. Neither report indicated the actual number of test kits used.

Forecasts are made according to the following VCT serial testing protocol:

<i>First test:</i>	Determine (RTD)
<i>Second test:</i>	HIV-spot (to be replaced by Rapitest (RTD))
<i>Tie breaker:</i>	Vironostika (ELIZA) at regional level and Public Health Laboratories

It is expected that a certain percentage of tests performed in the VCT centers will require a tie breaker test that is conducted at the Public Health Reference Laboratory using Innolia for inconclusive results. Forecasts of test requirements do not, however, differentiate the percentage required for tiebreaker testing. It is also unclear if forecasts include a recommended percentage of tests required for quality control testing (5 percent–10 percent).

The PHRL supplies HIV tests to health facilities for all purposes. There are no apparent stockouts of test kits and, based on anecdotal information, there may actually be an oversupply and possibility of expiry. However, a stock survey was not conducted as part of this assessment. The tests used and testing protocols are included as annex 6 to this report. Forecasts prepared for the annual procurement plan for HIV tests are based on the annual consumption (issues) from the previous year plus 10–25 percent for service expansion. Forecasts are prepared by the PHRL and submitted to SSDM for procurement.

### ***Nevirapine for Prevention of Mother-to-Child Transmission***

The Reproductive Health Unit serves as the program management unit for PMTCT. Currently PMTCT is available at two health facilities: the Start Program sites in Manya Krobo. The plan is to expand to a total of 32 sites as follows:

- two sites at Manya Krobo
- two sites each at Korle Bu and Komfo Anokye Teaching Hospitals
- twenty sites at district facilities
- six sites at Noguchi with support from the EU
- two sites funded by WHO.

The RHU bases the forecast for NVP on estimates of expected attendance at antenatal care clinics at the sites, and applies the HIV prevalence rate to that figure to estimate the number of pregnant women who are predicted to be HIV+. They assume that 100 percent of those predicted to be HIV+ will accept VCT, be tested, and, when found positive, would take NVP. RHU has set an initial target that each PMTCT site will provide NVP to 250 women per year.

Initial forecasts for NVP have been higher than program uptake. Reports from Manya Krobo indicate that in the eight-month period between July 2002 and February 2003, 45 pregnant women tested positive at Atua Hospital. The actual cumulative number who accepted NVP is not recorded. In the same period, St. Martin's Hospital has identified 172 HIV+ pregnant women, all of whom have received NVP.

Boehringer Ingelheim (BI) is currently the supplier of NVP for PMTCT through its donation program. Subsequent shipments will be based on progress reports submitted to BI by the RHU. Reporting by facilities will need to be adapted to ensure that essential logistics data is collected from the PMTCT sites, and that forecasting and quantification is based on consumption data.

Nevirapine is also being procured with Global Fund money. Care will need to be taken to ensure that the logistics data collected and reported from the sites reflects consumption of the donated versus the procured product to avoid double-counting that could result in inaccurate forecasts.

### ***ARVs for Antiretroviral Therapy***

Forecasts for ARVs have been prepared by NACP based on plans to provide ART to 6,000 patients a year for the next three years using the standard treatment protocols detailed in the MOH/GHS *Guidelines for Antiretroviral Therapy in Ghana*. The treatment protocols are in the annex. See table 2 for the initial estimates for the ARV drugs required, which was prepared by NACP.

**Table 2: Specific Drug Requirements as Calculated by NACP**

Drug	Estimated Number of Beneficiaries	Dosage/ Day (pills)	Quantity/Year	Remarks
Zidovudine	6,000	6	13,140,000	Assumes all treatment naïve patients will receive this. <sup>6</sup>
Lamivudine	6,000	2	4,380,000	Assumes all treatment naïve patients will receive this.
Efavirenz	6,000	3	6,570,000	Assumes all treatment naïve patients will receive this.
Stavudine	6,000	2	4,380,000	Assumes all treatment naïve patients will receive this.
Nevirapine	2,000	2	1,460,000	Assumes all treatment naïve patients will receive this.
Indinavir	500	6	1,095,000	Persons not responding to first-line therapy.
Nelfinavir	500	9	1,642,500	Persons not responding to first-line therapy.

Note: Table reproduced from table provided by NACP, no adjustments made.

There are a number of issues related to this initial forecast prepared by NACP:

- The specific protocol that will be used as the first-line treatment should have been established before calculating the quantity requirements. For example, patients would be started on zidovudine, lamivudine, and efavirenz.
- The quantity of stavudine is overestimated. As an alternate first-line drug, it will be used when zidovudine is not acceptable, or as a second-line when first-line treatments fail. Thus, the quantity of stavudine in the drug requirements, as calculated by NACP, should be reduced.
- Each dosage of a drug should be forecasted separately. For example, forecasts should be made for the 100 mg and 300 mg zidovudine tablets, always considering the pill burden to the patient. Dosage of stavudine is based on the patient's weight. Based on current clinical experience, most patients will initially require 30 mg tablets and will move to 40 mg as they gain weight. Forecasts should take into account the percentages of each dosage required.
- Didanosine (125 mg, 200 mg) has been omitted from the forecast as a second-line drug.
- The figures for the drugs indinavir and nelfinavir indicate an estimate of 8.3 percent of patients experiencing severe adverse side effects. This figure is too low. Based on discussions with local HIV/AIDS clinical experts, an estimate of 15 percent of patients who experience adverse drug reactions will require an alternative first-line drug.
- Indinavir is not an appropriate second-line drug with didanosine.
- The dosage indicated for nelfinavir is nine pills, 750 mg taken three times a day. To reduce frequency of drug administration to twice a day, 1250 mg (five pills) could be taken twice a day to facilitate drug adherence.

<sup>6</sup> These quantities are based on the assumption that patients receiving ART for the first time will be given these drugs.

In preparing forecasts for FHI-funded ARVs for 100 patients at Manya Krobo for six months using Combivir (zidovudine and lamivudine) and NVP, FHI estimated that 30 percent of HIV+ patients in clinical care would be eligible for ARV. FHI also expects that of the 100 patients, 15 percent will have an adverse reaction and require alternate drugs—a different estimate from that used in the MOH/GHS forecasts.

As no ARVs are currently in use in the public sector, a logistics-based forecast is not possible.

## **Finance**

Ghana's comprehensive HIV/AIDS response has identified and mobilized funding from multiple sources to support its programs. The four main sources of funding for support of ART in the country are presented below:

### ***GARFund***

The Government of Ghana has obtained a credit facility from the World Bank, IDA, to support the activities of the multi-sectoral response to HIV/AIDS. The funds, obtained under the World Bank's MAP assistance, amounting to \$25 million over three years, is to serve as seed financing for the GAR Fund. The Ghana AIDS Commission administers this fund and has since mobilized additional funding for its activities. There is a high likelihood that there will be an extension or a renewal of this funding mechanism under the MAP II. ARV procurement will be possible under MAP II funding. The Commission has also obtained an additional grant amounting to Great British Pound (GBP) 20 million from the UK Department for International Development (DFID). Other donors/development partners have provided funding, including, USAID, DANIDA, and the Dutch. Local donors to date include Coca-Cola and Barclays Bank.

It currently remains unclear how these funds will be coordinated for the procurement and supply of ARVs for PLWHA. No mechanisms have been defined for this.

### ***FHI/USAID***

USAID and FHI have committed some funds for the procurement of ART drugs for selected patients to be treated at the pilot sites of the Start project in the Manya Krobo District of the Eastern Region. The total number of patients expected to benefit under this package will number about 100 over a six-month period. Under this initiative, FHI provided funds to the MOH/GHS to effect the procurement. In addition, USAID has provided funds to FHI for a one-time shipment of antiretroviral drugs for 200 patients for one year.

### ***Global Fund***

Ghana is one of the first countries to be granted an award from the GFATM. Under the Global Fund proposal, Ghana intends to provide ART for 2,000 PLWHA. Procurement processes have already been initiated to purchase ARVs with these funds and the drugs are expected to be available in country within the next six to eight weeks. There is some possibility that Ghana will present another proposal to the Global Fund under the third request for proposal for additional funds for procurement of ARVs.

### ***Health Fund/Internally Generated Funds***

The MOH/GHS is operating a basket funding mechanism under the sector-wide approach. Using this framework, development partners provide budgetary support to the MOH/GHS to implement

previously agreed-to programs of work. The partners and the Ministry progressively review the implementation of work, based on agreed-to performance indicators and financial reporting through a standardized statement of expenditures.

Under the budget and program of work for the current medium-term health strategy, the MOH/GHS intends to apply funds from the pooled funds to finance the provision of ARVs for up to 4,000 PLWHA.

### **Local Production**

Long-term planning for ARV supply availability includes the establishment of local production. Discussions to date include a WHO-sponsored technology transfer from the Thai Government. There is no general consensus among stakeholders that this is the appropriate direction for long-term ARV security. Concerns that have been raised include the lack of local capacity for quality assurance, the size of the potential market, issues relating to World Trade Organization-Trade Related Aspects of Intellectual Property Rights (WTO-TRIPS), and possible changes in ARV regimen.

### **Cost to Client**

As of now, no policy has been accepted on the cost of ART to the patient. Ghana has a strong tradition of *cash-and-carry*, however, the cost of ARVs will be unaffordable to most Ghanaians. NACP has submitted a proposal to the Director General of MOH proposing that patients pay 10 percent of the total cost. No specific plan has been proposed for how the 10 percent of costs, if collected, will be used.

### **Procurement and Quality Assurance**

The goals for ARV procurement as stated in the national guidelines are to—

- Obtain the lowest possible purchase price.
- Ensure reliability of the supplier to supply good quality products and back them with adequate services.
- Minimize loss of resources, e.g., of funds and goods, resulting from adverse influences on procurement decisions and processes.
- Obtain optimum economy in personnel, time, and other resources used in the procurement process.

As part of key interventions in the health sector under the first five-year medium health strategy, procurement was identified as one of the areas for support. The MOH, with funding from the Royal Netherlands Embassy, obtained technical assistance to set up a procurement unit.

The Procurement Unit, located in the Procurement and Supply Division of the Ministry of Health, has developed and implemented a reform of the procurement processes and procedures within the health sector. A procurement manual has been produced and disseminated, and extensive in-service training has been conducted at all levels of the health sector.

Part of the objectives was to develop transparent procurement procedures and practices that are acceptable to both donors and the GOG. This was a partial requirement for participation by a number of the development partners in the common basket financing mechanism under the Sector-Wide Approach (SWAp).

Annual external post-procurement review has been conducted, and there is evidence that the Ministry has made significant progress in this area. Currently, the Ministry manages a significant procurement portfolio for goods and services at the central level.

The Ministry has conducted International Competitive Bidding for essential drugs and non-drug consumable supplies annually over the past five years, and has obtained, on average, prices of about 68 percent of the international median prices.<sup>7</sup> However, it has no previous experience in the procurement of ARV drugs. The Ministry is currently in the process of procuring its first batch of ARV drugs.

For the scale-up plan to treat 2,000 patients, the MOH has elected to procure ARVs from WHO pre-qualified suppliers through a limited tendering process, and has invited offers from the UNICEF Supply Division, Copenhagen; and the International Dispensaries Association, The Netherlands.

### ***Boehringer Ingelheim NVP Donation Program***

The MOH has taken advantage of the Boehringer Ingelheim (BI) donation program for prevention of vertical transmission (PMTCT). Under the program, the Ministry receives donations of both adult and pediatric formulations of nevirapine.

### ***Pfizer Diflucan Partnership Program***

Ghana is also the beneficiary of another donation program, the Diflucan Partnership Program of Pfizer. Diflucan (fluconazole) is donated for the treatment of OIs. Pfizer has specified requirements for reporting the use and stock levels of Diflucan by the FHI Start pilot sites and other sites.

### ***Quality Assurance***

The quality assurance system at present requires that the products be registered in the country of origin and have a certificate for free sale. The Ministry also requires a WHO/Good Manufacturing Practices certificate from the manufacturer and a manufacturer's authorization when procurement is through a wholesaler. Ghana also requires that imported drugs first be registered by the Food & Drugs Board. This requires the submission of relevant dossiers on the product. As part of the registration process, samples are obtained for testing.

Post-marketing surveillance is poor. The Food & Drugs Board is expected to take periodic samples of imported products from the marketplace for testing, but the cost of testing is prohibitive and undermines quality assurance.

### ***Distribution***

A number of different supply chains exist for the management of HIV/AIDS commodities in Ghana.

### ***HIV Tests for Voluntary Counseling and Transmission***

All HIV test kits are currently received by the CMS and are then stored at the PHRL. The Deputy Director of PHRL currently takes personal responsibility for monitoring test usage at the two VCT sites in Manya Krobo and for delivery of tests to these sites twice a month. If at any time the sites feel that stocks are running low, they call PHRL and can receive test kits within 24 hours. The quantity

<sup>7</sup> Procurement Review—post procurement review 2002.

distributed to the sites is based on the number of tests used since the previous delivery, plus 10 percent for service expansion.

Other health facilities pick up test kits at PHRL, generally on a quarterly basis, though more frequently should supply levels run low. Facilities receive the required number of kits each time they pick up supplies based on the number of kits they have used previously.

### ***Nevirapine for Prevention of Mother-to-Child Transmission***

Boehringer Ingelheim (BI) currently donates nevirapine (NVP) for PMTCT, both tablets for mothers and syrup for infants. CMS receives the donated NVP and transfers the stocks directly to the two service sites at Manya Krobo. Nevirapine is also being purchased using the Global Fund grant and current plans are for CMS to distribute the purchased product in the same manner as the donated product.

### ***ARVs for Antiretroviral Therapy***

While ARVs have not yet been received in-country for public sector facilities, plans for initial storage and distribution have been formulated. ARVs consigned to the MOH will be received and cleared by government clearing agents and transferred to the CMSs in Tema for repackaging and direct distribution to the planned service sites. The CMSs will transport the ARVs directly to service sites.

NACP will be responsible for determining what quantity of each ARV should be distributed to each of the service sites. Specific procedures for determining these quantities have yet to be developed. For the initial shipments of ARVs, which are due to arrive by April 30, 2003, all ARVs will be transferred to the two Start Program service sites in Manya Krobo. NACP will be responsible for informing SSDM by memo of the quantities to be distributed, and, in turn, SSDM will direct the CMSs by memo to make the distribution.

In addition to physical security offered by the storage facilities of Central Medical Stores, standard stock keeping and transaction records will be used to ensure full accountability of the drugs. While the duration of storage of ARVs in the CMSs will be limited, stock cards will be used to record the quantities of drugs held in the CMSs. Issue vouchers and waybills will serve as documentation of the transfer of commodities from the CMSs to the service sites.

### **Private Sector**

In addition to MOH facilities providing ART, Pharm Access International (PAI), and the USAID-funded CMS have developed a project to assist in the establishment of private sector treatment facilities for ART, and to promote the use of such facilities by private employers. Drugs sufficient for first-line ART are registered and being imported at prices that should permit retail purchase of triple therapy for \$3 a day or a bit more. At least four Cipla products and Combivir of GSK are being imported on this basis. They are currently available in pharmacies or will be soon.

PAI is working with three sites in Accra (Akai House Clinic, Nyaho Clinic, and Holy Trinity Hospital) to prepare them to provide ART by June 2003. Akai House is already providing ART to eight patients. PAI will be providing clinical training for physicians, medical and laboratory consultation, and quality monitoring. CMS will arrange training for counselors and will work to inform Ghanaian employers of the availability and cost of the ART service, and to assist interested companies in developing policies that will facilitate the provision of this service. Discussions are also underway with Ashanti Goldfields and Unilever about the possibility of supporting ART treatment at their corporate medical facilities.

PAI will also be working with at least one site (Medlab) to develop the capacity to do CD4 and viral load tests, and may assist in the development of laboratories at the other sites, depending on the ability of these facilities to invest in the necessary equipment.

The protocols that PAI uses are consistent with the published national ART treatment guidelines for Ghana. PAI plans to help the treatment sites install a computer system to monitor the cases receiving ART treatment, and will share this information with NACP.

## II. Facility Level

### HIV/AIDS-Related Services

#### ***Voluntary Counseling and Testing in Manya Krobo***

VCT activities at St. Martin's and Atua Hospitals commenced in July 2002.

**St. Martin's Hospital:** As of February 2003, 949 clients have been tested. Any symptomatic patient, presenting with an HIV-related illness, is referred by a clinician to the VCT service for pre-test counseling, testing, and post-test counseling. Out of the 949 clients tested, 285 (30 percent) at St. Martin's tested positive.

Twenty-four trained counselors offer VCT services, but two counselors have shown signs of burnout and are no longer actively involved in counseling. The matron, who heads the counseling unit, is involved in training of counselors and monitoring their performance. Counselors are nurses who still perform their usual duties, but, on the day they are scheduled to counsel clients, they only do counseling. On average, a counselor handles six clients on his/her counseling day. Counseling is offered as a 24-hour service at St. Martin's, five days per week, except Fridays and Sundays. Saturday is the market day in Agomanya, so staff at St. Martin's are off duty on Friday and work on Saturday to satisfy the influx of patients and clients coming into town. Counselors also take the usual call duties and, while on call duty, they offer counseling services to clients.

Counselors are not authorized to perform rapid HIV screening tests. They collect a blood sample from the client and take it to the laboratory for testing. Determine and HIV-spot are used in a serial protocol, with same day results provided. When results are discordant, a tiebreaker test is done at the Public Health Research Laboratory using Immunoblot as the confirmatory test. Results of the tiebreaker test are given to clients within two weeks. On average of 100 clients are tested at St. Martin's each month. St. Martin's receives funds for VCT support from FHI. At the moment VCT is offered free of charge.

**Atua Government Hospital:** Atua Government Hospital has a well-established VCT service with trained nurse counselors. A review of reports over the past few months indicate that uptake of the VCT services available at the hospital is encouraging. From July 2002 to February 2003, 652 clients were tested, of which 288 (44 percent) tested positive. An average of five to six clients are counseled per day. Atua Hospital VCT operated Monday through Friday 8 a.m. to 5 p.m. VCT clients belong to three main categories: walk-in clients; those referred by CBOs and NGOs; and, finally, patients suspected of presenting clinical HIV-related diseases.

### ***Prevention of Mother-to-Child Transmission of HIV***

PMTCT services started in November 2001 and are integrated into maternal and child health (MCH) services in Manya Krobo. Nurses inform pregnant women attending antenatal clinics of the VCT services available and the risk of transmission of HIV to the baby. Mothers are also provided information on nutrition, breastfeeding, and substitute formula feeding. HIV-positive mothers who decline breastfeeding, are trained on skills for proper formula feeding. Mothers who choose to breastfeed are advised to give exclusive breastfeeding for four to six months and not to wean abruptly. Furthermore, they are counseled on the most appropriate position to hold the baby to reduce the risk of sub-clinical mastitis.

There are six health providers who offer PMTCT services at St. Martin's Hospital. They were trained last year and work seven days a week. There are three antenatal clinics every week. As of February 2003, 1,775 pregnant women were informed about PMTCT service; 1,374 (77.4 percent) accepted HIV testing; and 172 pregnant women (12.5 percent) were HIV-positive.

Atua Hospital provides VCT services to most antenatal attendees at the hospital. During a 14-month period, 1,123 new attendees visited the antenatal clinic at Atua Hospital, an average of 80 new attendees per month. Of the 434 pregnant women screened for HIV, 45 were HIV positive (10.4 percent). It was reported that about one-third of acceptors delivered at home. This greatly undermines the successful implementation of the program.

Nevirapine is offered when labor starts, and nevirapine syrup is given to the baby born of an HIV-infected mother up 72 hours postpartum. Health providers reported a few cases when babies have been brought to the hospital several days after the 72 hours cut-off point for prophylactic therapy for the baby. In the case of false labor, the parturient takes another tablet of NVP at the onset of labor. Twenty-five of pregnant women deliver in a health facility. A high percentage of pregnant women deliver at home because they cannot afford to pay hospital charges (normal delivery for U.S.\$10 and caesarean section for U.S.\$ 75–\$120), because of the distance from a health facility, especially at night where there are no means of transport, and other reasons.

St. Martin's and Atua Hospitals receive support for PMTCT from UNICEF, Noguchi Memorial Institute for Medical Research and FHI. Formula will soon be distributed by the RHU and funded by FHI to HIV-positive mothers who elect not to breastfeed their infants.

In the other institutions visited, counselors were trained in 1998–2000 and have not received any additional training since then. Limited counseling services exist for HIV testing for clinical diagnostic purposes. In general, VCT has not been actively promoted. By the end of 2003, the focus will be to create 16 VCT/PMTCT sites.

### ***Adherence Counseling***

Twenty-one health workers will be trained on adherence counseling in April–May 2003. These counselors will be charged with doing pre-treatment counseling, home visits for verification of residential address, and identifying individuals to whom a patient on ART has disclosed that she or he is suffering from AIDS. Counselors will also follow-up on effective compliance to prescription, early detection of side effects from medication, as well as reasons for not reporting for follow-up at the health facility or refilling her or his prescription.

### ***Home-Based Care***

St. Martin's Hospital, with the backing of the Catholic Mission in Manya Krobo, has recently started home-based care services using volunteer nurses and lay counselors to care for patients with advanced stages of AIDS. Home-based caregivers provide this service either early morning before work or after work in the evening, and receive reimbursement for their transport. These caretakers help by providing food, feeding the patients, cleaning them, taking care of bedsores, providing medication, and other services. This service was previously conducted in the lower part of the catchment area and is now being revived and expanded to cover the rest of the sub-district. Catholic Relief Services (CRS) intends to provide food for HIV patients, orphans, and other vulnerable persons.

Apart from the St. Martin's Hospital home-based care program, FHI is supporting the Catholic Diocese of Koforidua through the St. Martin's Mission to provide a community model home-based care system. The service will use volunteers from the communities.

Communities and households have not adjusted to the idea that they need to attend to and care for PLWHA as any other patient, without any feeling of stigma attached to the infected person. Home-based care remains the least developed component of the National HIV/AIDS Strategic Plan and requires special attention.<sup>8</sup>

### ***Sexually Transmitted Infection Management***

Patients presenting with STIs are diagnosed and treated using the syndromic management approach. This integrated service is offered through the outpatient department. In February 2003, nine health workers were trained on syndromic management of STIs with funding from CIDA. St. Martin's is a sentinel surveillance site for STIs and is reported to have a good record for STI services.

In the National Strategic Plan in 2002–2006, syndromic management of STIs is the first-line strategy for STIs in both public and private health institutions, including pharmacy and chemical shops. STI management at the primary level is integrated into routine health services. Specialized services are provided in regional and teaching hospitals. The MOH plans to strengthen the management of STIs by revising guidelines and providing training and supervision to providers. Laboratory diagnosis of STIs will be limited to treatment failures. The MOH plans to establish sentinel sites for STI surveillance for the spectrum of STI organisms and their drug sensitivity. An STI program will be designed for commercial sex workers. STI drugs are currently bundled with condoms for CSWs by NACP and should be promoted on a larger scale. In addition, universal syphilis screening for ANC attendees is being introduced.

### ***Management of Opportunistic Infections***

OIs represent a major cause of ill health and death for PLWHA. A curriculum for training health professionals on the management of OIs has been developed. In January 2003, FHI provided a national workshop for training-of-trainers for OI management. A total of 16 participants from all over Ghana took part, including physicians, nurses, and pharmacists. Out of this group, four physicians, one pharmacist, and senior nurses from Manya Krobo participated. Downstream training on management of OI was organized for 45 health workers in Manya Krobo and Yilo Krobo districts. OI management is integrated into the clinical services of Manya Krobo hospitals and is offered five days a week. Trained health workers, who prescribe medication and provide counseling for positive living, provide most clinical treatment of OIs. The hospital holds HIV/AIDS clinics on Monday and

<sup>8</sup> Ministry of Health, Ghana. *HIV/AIDS Strategic Plan MOH/GHS, 2002–2006*. October 2002. Revised on April 8, 2003.

Thursday morning when an additional clinician from FHI joins the hospital-based physicians to attend to HIV/AIDS patients. The clinic is said to be very well patronized with weekly attendance reaching a maximum of 17. On average, there are 5–10 patients per clinic day.

Cotrimoxazole prophylaxis against *Pneumocystis carinii* pneumonia, toxoplasmosis, bacterial pneumonia, and diarrhea is generally given for life. However, for patients on ART, prophylaxis with cotrimoxazole is discontinued if the CD4 cell count for at least three months is  $>200$  cells/ $\mu$ L. Additionally, fluconazole (Diflucan), donated by Pfizer Laboratories, is provided for chemoprophylaxis and treatment of cryptococcal meningitis and esophageal candidiasis. Vaccines are administered according to the national immunization schedule. Chemoprophylaxis of tuberculosis is not recommended in Ghana.

Patients presenting with an acute OI will be treated for the infection before initiation of ART.

### ***Tuberculosis***

St. Martin's and Atua Hospital have the capacity to diagnose and treat TB cases. Ten health care workers from St. Martin's and seven from Atua were trained in March 2003 on TB diagnosis and treatment. TB is reported to be one of the most prevalent OIs among HIV-infected individual. There is an effort by the Start Project sites to actively screen for TB among HIV-infected individuals for early case detection and management. Diagnosis of a case of TB is based on three acid-fast bacilli (AFB) sputum tests. If the sputum test is negative, a chest x-ray is requested. Patients are not treated on clinical diagnosis alone. Directly observed treatment short-course (DOTS) is implemented during the intensive care period of two months; the patient reports daily for observed treatment.

### ***Antiretroviral Therapy***

Protocol and guidelines have been developed and data collection forms were designed and tested. Adults and children will be included into the program at the initial phase.

Neither institution has started dispensing ARVs. They are expected to arrive by the end of April 2003. A week before arrival, all health workers who were initially trained in prescribing, patient monitoring, and care in November 2002, will receive a refresher course. This pilot phase of ART is expected to last for six months. FHI and USAID have provided initial support for the ART program. Subsequent support will be provided through the Global Fund.

Two clinicians and a pharmacist in Atua and two clinicians at St. Martin's have been trained on ARV prescribing and management of patients on ART. The dispensing technician at the pharmacy will also be trained. St. Martin's intends to implement a modified DOTS model whereby the treatment will be observed by the designated confidant. The initial two weeks of ARV therapy will be closely monitored because, during this period, the patient usually feels worse before feeling better.

Table 3 lists the criteria for inclusion into the program:

**Table 3. Criteria for Inclusion in Program**

<b>Biological Criteria</b>	
Adults	<ul style="list-style-type: none"> <li>• WHO Clinical Stage III or IV.</li> <li>• CD4 &lt;250.</li> <li>• Normal liver and renal function test results.</li> </ul>
Children	<p>The child must meet any one of the following:</p> <ul style="list-style-type: none"> <li>• Symptomatic children in Pediatric Stage II and III whose mothers are HIV positive.</li> <li>• CD4 &lt;20 percent in child less than 18 months.</li> <li>• CD4 &lt;15 percent in child more than 18 months.</li> </ul>
Diagnosis must be confirmed by polymease chain reaction (PCR) in children less than 18 months. For those over 18 months, antibody tests will be used.	
<b>Social Criteria</b>	
All of the following must apply:	<ul style="list-style-type: none"> <li>• Patient must disclose their serostatus to supportive relation or friend.</li> <li>• Patient (parent in the case of children) must attend at least one session (preferably two to three sessions) of pre-treatment counseling before initiating ARV therapy.</li> <li>• Patient or caretaker or parents must reside in and be able to provide the exact location of their residence in Manya Krobo or Yilo Krobo.</li> <li>• Patient, caretaker, or parents must provide the name of a contact person and an exact location/verifiable address.</li> <li>• One pre-treatment visit to verify location residence must be made by a health worker before initiating therapy.</li> </ul>

### ***Patient Load***

As of February 2003, there were 125 patients who qualified for ARV in Manya Krobo. No children were included in the initial number of patients to whom ARV drugs will be dispensed. Selection of ARVs was based on the national protocol, and quantification was based on the 100 first patients to be treated. It was estimated that 15 percent of patients under ART will present with severe adverse effects and toxicity and will require an alternate treatment regimen that would require a single-drug substitute, not a complete change of regimen.

### ***Laboratory Support Services***

All laboratory services except CD4 and viral load are conducted on site. The tests include full blood count, total lymphocyte count, urinalysis, routine stool examination, liver function tests, blood urea, electrolytes and creatinine, and HIV screening.

For VCT or PMTCT, blood is drawn by the nurse counselor and sent to the laboratory where a laboratory technician does the first test using Determine 1&2. If reactive, the test is confirmed with a HIV spot test. If discordant, the sample is sent to the PHRL. All positive samples are sent to the PHRL for strain typing (HIV1, 2, or dual infection 1&2). The distribution of HIV strains in Manya Krobo is similar to the national trend. VCT and PMTCT services are offered free during this pilot phase. FHI pays for the testing.

Samples for CD4 and viral load measures from Manya Krobo hospitals will be transported three times a week to Noguchi Memorial Institute for Medical Research Laboratories in Accra. Noguchi will make the transport arrangements and provide results within 72 hours to the hospital laboratories. The laboratory technicians will inform the clinicians.

During the initial stages of the ART program expansion, the MOH hopes to establish diagnostic centers capable of monitoring CD4 and viral load in regional and teaching hospitals. Several private laboratories already provide these tests, though actual testing is done in South Africa. For the public service, HIV testing supplies are provided by the PHRL or purchased by the health facilities from local retailers of laboratory reagents and supplies.

### ***Logistics Management Information System***

A complete and effective logistics management information system (LMIS) includes the accurate recording of logistics data on stock keeping, transaction, and consumption records. These records are used to collect information on the essential logistics data items: stock on hand, commodities dispensed to users, and losses and adjustments to stock. These data items are then reported in a complete and timely manner for operational decision making for resupply, forecasting, and procurement, and for monitoring availability of commodities and evaluating program effectiveness.

Current facility level stock keeping records (tally cards) include balances, receipts, issues, transaction reference, dates, item description, and, in some cases, additional information such as maximum and minimum stock levels. Losses and adjustments are not tracked. From the assessment, tally cards appeared to be generally well kept and stock balances matched physical inventories.

*Issue Vouchers* and *Combined Requisition and Issue Vouchers* are the main transaction records used. These records contain the requisite information to account for the transfer of commodities from one facility to another.

The weakness in the current public sector recording system lies with the consumption records. The quantity of each HIV/AIDS commodity given to the client, in some cases, is recorded only in the patient's medical folder; in other cases, in a prescription register. While the national ART guidelines specify the use of a prescription register, which would include the quantity of drugs dispensed to each patient, use of these registers for other drugs is currently inconsistent. There is no systematic collection of consumption data by commodity. The exception is the current system used to record the consumption of Pfizer donated Diflucan (flucanazole). For this product, a separate register is maintained and the date, name of patient, prescriber, and quantity of product dispensed is recorded. A similar register is used for NVP, with the exception that the quantity of NVP dispensed is not recorded, the assumption being that each patient is given one tablet.

The majority of reporting on HIV/AIDS programmatic activities is on services provided and clinical status of patients. Reports submitted by the Start Program sites are submitted monthly. Little or no logistics data is reported and, when reported, it is difficult to interpret and there are inconsistencies between reports. In general, there is a significant lack of logistics data and information collected and routinely reported for management of HIV/AIDS commodities.

For future management of HIV/AIDS commodities there is a great need for the systematic reporting of stock on hand, quantities dispensed, and losses and adjustments. PPME/GHS reports an 80–90 percent reporting rate for health services monthly returns using standardized forms. This compliance in reporting bodes well for the possibility of routine collection of logistics data from the facility level.

At the private sector clinics visited, stock levels and information on drugs dispensed are maintained in computerized information systems, which facilitates routine access to LMIS reports.

### Site Readiness to Provide Antiretroviral Therapy

Each of the service sites was assessed on its capacity to provide HIV/AIDS-related services and to manage the commodities needed to support those services. Site by site findings and recommendations can be found later in this report. The table below indicates the scores each facility earned by domain and by factors within the domain using the Stages of Readiness Assessment Tool. A copy of the tool is included as annex 4 to this report.

An average domain score of 5 indicates a program is most ready to go. A score of 1 indicates that the program needs significant work and planning to be able to start and manage an ART program. It is recommended that a site needs to have at least a score of 3 in each domain to begin ART, and preferably a 4.

The Total Average Domain Score indicates the Stages of Readiness of the facility to initiate antiretroviral therapy.

Total Average Domain Score	Stage of Readiness
1–8	Stage 1—Program Mobilization
9–13	Stage 2—Service Delivery Planning
14–18	Stage 3—Preparation
19–24	Stage 4—Action
25–30	Stage 5—Support, Maintenance, and Expansion

Table 4. Results of Stages of Readiness Assessment Tool

	Atua Government Hospital	St. Martins Catholic Hospital	Korle Bu	Komfo Anokye	Akai House Clinic	Nyaho Clinic	Holy Trinity Hospital	AGC Hospital
<b>Leadership</b>								
• Leader	4	4	3	2	4	4	4	3
• Model of Care	4	4	2	2	4	3	3	2
<b>Average domain score</b>	<b>4</b>	<b>4</b>	<b>2.5</b>	<b>2</b>	<b>4</b>	<b>3.5</b>	<b>3.5</b>	<b>2.5</b>
<b>Services</b>								
• ART	3	3	3	2	3	3	3	2
• Comprehensive Services	4	4	2	2	3	3	3	2
• Physical Space	5	5	4	1	5	3	3	3
• Community Involvement	5	5	2	1	1	1	2	2
<b>Average domain score</b>	<b>4.25</b>	<b>4.25</b>	<b>2.75</b>	<b>1.5</b>	<b>3</b>	<b>2.5</b>	<b>2.75</b>	<b>2.25</b>
<b>Program Protocols, Management, and Evaluation</b>								
• ART Protocols	5	5	3	3	4	4	4	2
• MIS	4	4	2	1	5	2	2	3
• Program M&E	4	4	2	2	3	2	2	2
<b>Average domain score</b>	<b>4.33</b>	<b>4.33</b>	<b>2.33</b>	<b>2</b>	<b>4</b>	<b>2.66</b>	<b>2.66</b>	<b>2.33</b>
<b>Experience and Staffing</b>								
• Experience	3	3	4	2	3	3	3	3
• Management Training and Retention	5	5	3	2	4	4	4	4
<b>Average domain score</b>	<b>4</b>	<b>4</b>	<b>3.5</b>	<b>2</b>	<b>3.5</b>	<b>3.5</b>	<b>3.5</b>	<b>3.5</b>
<b>Lab Capacity</b>								
• Testing Capability	4	4	4	4	5	4	4	3
• Quality Standards	4	4	4	4	5	4	4	4
<b>Average domain score</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>5</b>	<b>4</b>	<b>4</b>	<b>3.5</b>
<b>Drug Management and Procurement</b>								
• Supply Chain	4	3	4	2	4	4	4	4
• Pharmacy Management	3	3	3	3	4	4	4	3
• Financial Resources for ARV and Other Drug Procurement	5	5	5	4	4	4	4	4
<b>Average domain score</b>	<b>4</b>	<b>3.67</b>	<b>4</b>	<b>3</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>3.67</b>
<b>Total Average Domain Score and Stage</b>	<b>24.58</b> Stage 4	<b>24.25</b> Stage 4	<b>19.08</b> Stage 4	<b>14.5</b> Stage 3	<b>23.5</b> Stage 4	<b>20.16</b> Stage 4	<b>20.41</b> Stage 4	<b>17.75</b> Stage 3

# Conclusions and Recommendations

The recommendations of the assessment team are presented under the following two general categories: logistics management recommendations; and policy, program, and service recommendations.

## Logistics Management

1. NACP needs to appoint and seek assistance to train an HIV/AIDS logistics manager to be responsible for the coordination of commodity forecasting; procurement and distribution of HIV/AIDS related commodities; and working in conjunction with all stakeholders, including private sector providers and funders.

The effective management of HIV/AIDS commodities is essential for the providing HIV/AIDS services across the continuum of care. ART, VCT, PMTCT, and treatment of OIs and STIs all require a consistent supply of quality drugs, test reagents, and other supplies. Laboratory reagents, supplies, and equipment must be available to identify and monitor patients who need ARV drugs. Condoms and contraceptives are needed for family planning and HIV/AIDS prevention.

The forecasting for and distribution of several HIV/AIDS products is currently managed by a number of different units within the MOH. The PHRL handles HIV tests for VCT, the Reproductive Health Unit manages NVP for PMTCT, and NACP has prepared the initial forecasts for ARVs. The NACP HIV/AIDS logistics manager will be responsible for formalizing the relationships and responsibilities of these units for commodity management and establishing mechanisms for routine communication and coordination. The HIV/AIDS logistics manager should—

- Coordinate with public and private sector providers and programs, and funders to ensure the uninterrupted supply of HIV/AIDS commodities.
- Finalize forecasts for HIV/AIDS commodities with all stakeholders.
- Coordinate with SSDM and the Procurement Unit to facilitate commodity procurement.
- Direct the distribution of commodities to the services sites based on analysis of reports from the sites and program plans.
- Monitor stock levels to ensure a consistent supply of HIV/AIDS commodities in the country and at the service sites.

The NACP HIV/AIDS Commodity Manager, with the SSDM, should also be responsible for coordinating with drug company donation programs, such as the Pfizer Diflucan Partnership Program, the BI nevirapine donation program, and others.

It is recommended that the NACP HIV/AIDS logistics manager attend the DELIVER Supply Chain Manager Course.

2. NACP should seek assistance to design and implement an LMIS to capture essential logistics data and track product use in the system. Standard formats should also be instituted for reporting service information.

The overall purpose of the LMIS is to prevent stockouts and stock imbalances of ARVs and other HIV/AIDS-related products at sites that provide HIV/AIDS services to clients. LMIS data should inform future forecasting of requirements and will help validate forecasts based on morbidity or other service methodologies. The LMIS, with service reports, provides a mechanism for verifying and reconciling of service data with commodity data, an important aspect of drug accountability. Routine access to LMIS data would also help with commodity management in other areas, including inventory control and distribution. The high costs of ARVs means that holding buffer stocks against uncertainties in uptake and changes in regime use has a high cost in terms of potential lives saved (essentially the higher the buffer stock you maintain, the fewer people you can treat). There is also a higher risk of pilferage if inventory levels are kept high. An agile and responsive LMIS and coordination with key stakeholders is critical for ensuring uninterrupted supplies while maintaining lower levels of stock, without compromising service.

The successful implementation of a cost recovery system for drugs over the past two decades by the public health sector in Ghana has significantly improved drug availability in the public health facilities. However, as financial accountability has become increasingly important, the need to account for each tablet or capsule has become less crucial. Managers have been innovative at designing or adapting the record keeping practices to track and ensure financial accountability at the dispensing points. While this has ensured that dispensing records are maintained, they are oriented towards financial and not commodity accountability. For instance, it is common to have daily summaries of total costs of commodities received and dispensed, but not the summaries of quantities of drugs dispensed. As Ghana contemplates abolishing the *cash-and-carry system* and eliminates fee for service at the dispensing interface, it is paramount to reorient the record keeping to meet this requirement.

An LMIS is also useful in providing data on how many patients are given first-line, alternate first-line and second-line drugs, not only to help resupply, but also to help the program monitor rational drug use and correct prescribing patterns. For example, if one site has an unnaturally high numbers of patients on alternate regimens, then NACP can follow-up and determine if the prescribers are doing their job properly.

It is also important to note that ARVs and related commodities for HIV/AIDS clinical care, such as nevirapine for MTCT, and diflucan for OIs would need to be accounted for differently and not necessarily by the financial value because these would either be subsidized or provided free to patients. As donors for these commodities would need data on consumption, the need to summarize and report dispensing records cannot be overemphasized.

While the reports from the services sites at Manya Krobo report service statistics regarding numbers of PMTCT patients, clinical status, and HIV tests performed, the information is reported in an inconsistent manner, making it difficult to interpret and compare information presented in the reports. As the number of sites providing essential HIV/AIDS services expands, it will be necessary to easily aggregate and use data from all service sites. Therefore, standard reporting formats should be developed and used for reporting service and logistics data. The report should be completed by all participating sites and essential data collected for all HIV test kits, nevirapine for PMTCT, ARVs, and OI drugs such as Diflucan.

The LMIS reports should include the following information:

- beginning stock balance
- receipts
- consumption (dispensed to patients)
- losses and adjustments (transfers to other sites, expiry, damaged commodities)
- ending stock balance (including quantities per expiry date).

To support accurate reporting of LMIS data, current record keeping systems need to be improved to gather this information. While not currently standard practice, the national ART guidelines required the use of a prescription register to record quantity of drugs dispensed, with other information. Establishing the use of such a register will be essential for capturing consumption data.

NACP should use this information to determine issue quantities, monitor stock levels, cross-check quantities dispensed with service statistics, plan procurement, and implement stock transfers when needed to avert stockouts and stock expiration. NACP should also provide regular logistics status reports to program managers, partner organizations, and commodity donors to maintain the confidence and financial support of the donor community and government policy makers. Assistance for implementation of this recommendation is available from the DELIVER project upon request.

3. The MOH should develop a strategic approach for the medium- to long-term security of a supply source for ARVs.

The costs of acquisition of ARVs have undergone significant changes during the past few years. There are a number of initiatives, both bilateral and multilateral, that have worked to significantly reduce the cost of ARVs. The global calls for increased access to ARVs have seen a number of initiatives including the donation programs of some manufacturers and concessionary pricing initiatives, from some branded manufacturers. Of particular interest are the donation programs of BI and Pfizer, of which Ghana has already taken some advantage. The supply of ARVs has been cited by many to bring into the public domain discussions with respect to the WTO-TRIPS and the relief options that are available to member nations under the Doha declarations of 2002.

The MOH should explore opportunities with other drug company donation programs such as the Abbott Determine HIV test donation program.

The option of local manufacture of ARVs have been suggested, and there are currently efforts under way to explore this possibility, with an offer for technology transfer from the Thai government.

As Ghana considers local manufacture, there is the need to thoroughly examine the options available for a secure supply of ARVs and to select the most cost-beneficial option. Important factors for consideration include—

- Donations and concessionary prices that can be obtained.
- Capacity of local regulatory authorities to ensure quality of local manufacture.
- Agility of local manufacturing to adapt to the development of newer approaches in ART, and the changes that can occur in the short to medium term in treatment protocols.

- Size of the potential market for ARVs locally and within the sub-region.

Similarly, it is important to determine whether local manufacture will be able to produce the full range of products in the national protocol or which components will still have to be imported.

4. NACP and the Procurement and Supplies Division should establish a HIV/AIDS Commodity Coordination Group to coordinate and improve methodologies for forecasting ARVs, HIV tests, and other HIV/AIDS-related commodity requirements, and to monitor the supply status of these commodities. This group should include all stakeholders involved in the provision of ART, including Government of Ghana entities, private sector providers, and funders.

Like any new program, the commodity requirements for ART in the country have been based on a non-rigorous forecasting methodology. While initial forecasts have been based on a target and service provision approach, several factors could not be considered. For instance, there is no basis for determining the number of patients who will need to be offered alternative treatment schedules because of toxicity or resistance or any other factors that can only be observed in the actual use of the commodities.

For future forecasts, the Coordination Group should assess present consumption pattern of ARVs, study reports on the rates of side effects, treatment failure, and success. The forecasts prepared should also consider respective quantities for adult and pediatric formulary.

HIV test kits have been managed by the PHRL for a number of years, but no logistics data has been collected as the commodities are being used and allocation has been based on tests performed in the reporting period instead of tests actually consumed during the period.

These examples just illustrate the weaknesses that could be inherent in the current forecasting processes. The design and implementation of an appropriate LMIS to capture, aggregate, and report commodity consumption has been mentioned earlier. NACP, working with the appropriate program managers, should establish a group that is responsible for forecasting for and routine monitoring of HIV/AIDS commodities. This group should seek technical assistance through USAID to improve these processes.

5. All HIV/AIDS commodities should be procured and managed by the MOH. The MOH should foster public-private sector partnerships to ensure effective procurement and distribution of HIV/AIDS commodities. The existing MOH procurement, storage, and distribution systems and alternative management systems should be reviewed. Weaknesses in the current systems should be addressed to ensure accountability and security for all health commodities to the satisfaction of all stakeholders.

As Ghana begins implementing ART, the chances that new systems will be developed to support ART-related activities are high. There is the need to guard against this occurrence and to build on the progress made in the development of a number of structures. Worth mentioning here are the procurement and supply chain structures developed by the MOH. While these may not be the ideal systems, they still represent the best options available for managing health commodities. It is highly recommended that these systems be used and strengthened to meet the long-term needs. Any interim plans at commodity procurement and management must be undertaken with a clear plan for its eventual integration into the main essential drug supply pipeline. In addition, the MOH should develop relationships with private sector providers of ART and determine the best way to coordinate procurement and distribution of drugs in both the public and private sector.

6. NACP and the Procurement and Supplies Division should develop interim procedures for management of ARVs, including procedures for issuing to service sites and a system for monitoring facility stock levels of ARVs. They should also develop a plan for the long-term management of ARVs.

It is a commonly agreed that when the first supply of ARVs arrive in the country, they will be allocated to pre-determined selected sites for use: pilot sites and scale-up sites. Other locations will be supplied with commodities as they become ready to initiate ART. This indicates that the use of the current distribution system, as is, may not be the most appropriate. In the short term, it is important that levels of the current distribution system that have no immediate role in the implementation of the ART should not be involved in the management and handling of the ARVs. Reference is being made to the levels such as the RMSs. The modified supply arrangement will be necessary to enable closer monitoring of the products to ensure their safety, remove the need for additional stocks that will be required to fill the supply pipeline for the levels identified earlier, and enhance the agility of the system to quickly respond to supply imbalances at the implementation sites. Care should be taken not to construe this as a recommendation for a new vertical or parallel distribution system for ARVs.

NACP and the Procurement and Supplies Division need to develop, document, and disseminate clear procedures for near-term supply management, including record keeping and reporting procedures for distribution to sites.

In addition, NACP and the Procurement and Supplies Division should begin discussions on plans for the eventual integration of ARVs into the existing supply chain for essential drugs.

7. NACP should coordinate the supply of ARVs and the provision of ART in both the public and private sector, with the possibility of a common supply source. The MOH should foster public-private sector partnerships providing ARTs to ensure wider access for those in need of treatment.

The need for uniformity in treatment protocols in both the public and private sector necessitates that both sectors coordinate the selection of ARVs and implementation of ART. Of major concern in many areas is the threat to a secure supply chain and the need to guard against the leakage of commodities from the public sector into the private sector. As has been demonstrated by the National TB Control program, it is possible to explore avenues of collaboration between the NACP and the private sector. One potential area of collaboration would be to provide private sector providers with the opportunity to purchase ARVs from the MOH supply chain.

In implementing this recommendation, NACP should liaise with the Food and Drugs Board to know what ARVs are licensed for import into the country. They should determine what treatment protocols are used in the public and private sector, and disseminate the national guidelines for ART to ensure uniformity. NACP should also explore opportunities to supply commodities to the private sector and collect private sector services statistics to fully understand the national provision of ART. Providing a source of ARVs to the private sector through the public sector can offer several advantages, including—

- Decreases incentives for diversion of ARVs from the public to the private sector.
- Controls the quality of ARVs.
- Standardizes ARVs available for treatment.
- Lowers cost drugs available to the private sector.

One consideration is the need for incentives for the private sector to participate in buying public sector drugs. One possible incentive that is being explored in Malawi, Kenya, and Uganda is accreditation and certification of private sector physicians and pharmacies to prescribe and dispense ARVs. One requirement of accreditation is providing data on patients treated and drugs dispensed.

8. Ghana AIDS Commission and NACP should identify a set of logistics system performance indicators to monitor the implementation of the ART supply system.

An efficient logistics system is necessary for successful implementation of ART. To determine the efficiency and effectiveness of the supply chain, appropriate indicators of performance need to be collected through the routine information system and analyzed by NACP. Performance indicators should include indicators on stock availability, stock status, stockouts, and product expiry and wastage. Feedback reports on performance should be provided to program and facility managers. This set of indicators would enable both NACP and the Ghana AIDS Commission to monitor the overall performance of ART services as a component of their care and support mandate and to take remedial action, if necessary.

## Policy, Program, and Service

1. The MOH should determine what the cost of ART will be to the patient and take the necessary policy actions.

The most crucial policy issue that remains outstanding, as frantic efforts are made to acquire commodities for ART, is the cost to the patients. It is obvious that the full cost recovery system by which most of the essential drugs in the public sector is managed cannot be transferred to ARTs. The true costs of ARVs are expected to be unaffordable for most patients who will require them. The National AIDS Control Program is in the process of obtaining the government's policy on meeting the costs of ARTs through appropriate channels. This process needs to be expedited as ART services are expected to begin in the next month.

The MOH should explore the possibility of introducing a sliding scale of pricing as a way to ensure equity. Under such a scheme, patients who can afford to pay do so, while those who cannot get drugs at subsidized cost. A consistent policy of pricing by private and public sector providers would be important to ensure that when there are changes in drug prices, patients are not prone to move from one sector to another. If regimes are not standardized between public and private providers, patients may switch from paying for more sophisticated regimes in the private sector to the cheaper and more basic regimes in public sector. While the public sector regimes would be effective on ARV naïve patients, they might not be on those who have already been exposed to more sophisticated drugs, thus wasting those drugs.

2. NACP needs to appoint an Antiretroviral Therapy Coordinator to ensure the rational and effective introduction of ARVs in the public sector, to monitor ART in the private sector, and to solidify the technical leadership of NACP in this area.

Currently, the NACP Program Manager is directing the ART initiative of NACP, but, because the program will require intensive effort and attention during its initiation and expansion, a focal person for ARTs who will report to the Program Manager at NACP, will be essential. The ART Therapy Coordinator should be responsible for coordinating the ART Program with other related programs, including PMCTC, VCT, TB, laboratory and other support services, training efforts, and resource mobilization. The coordinator should also work closely with FHI, DELIVER, and other technical

assistance providers to assess the readiness of potential health facilities to introduce ART and to prepare facilities identified to provide ART.

The NACP ART Therapy Coordinator should also establish the technical leadership role of NACP in working with private sector service facilities that provide AIDS care. NACP should offer assistance to private sector facilities providing ART, similar to the approach used by the TB Control Program to coordinate with private sector health facilities. NACP assistance to both public and private sector facilities should include dissemination of treatment protocols, training, establishment of standard operating procedures for management of and reporting on ARV drugs, coordination of drug procurement, and other activities, as needed.

3. The MOH/GHS should take steps to incorporate the *Guidelines for Antiretroviral Therapy* in the *National Standard Treatment Guidelines*.

The current *National Standard Treatment Guidelines* were reviewed and printed in September 2000. The chapter in the guidelines on HIV deals only with treatment of post-exposure prophylaxis. Because the *Guidelines for Antiretroviral Therapy* are now available, during the next review and update of the *Standard Treatment Guidelines*, it is recommended that the HIV chapter be expanded to include the ART guidelines.

4. NACP should work with the Food and Drugs Board and the Pharmacy Council to establish a mechanism for monitoring and regulating ARVs that are available through commercial pharmaceutical companies.

Twenty ARV preparations are currently registered for importation into Ghana, and ARVs are increasingly available in the commercial sector. The effective treatment of AIDS with ARVs requires careful dosage of the right combinations of drugs. The MOH/GHS has developed standard protocols for treatment with first-line drugs, alternative first-line drugs and second-line drugs when the patient experiences severe adverse reactions and resistance to first-line drugs. These guidelines are in accordance with WHO guidelines and have proven to be effective in other countries. NACP should disseminate ART protocols to private sector providers. Unregulated and indiscriminate use of ARVs without regard to treatment protocols and management of side effects can result in not only ineffective treatment of the individual patient suffering from AIDS, but can also create resistance to certain ARVs, limiting future options for treatment and having significant public health consequences.

The Food and Drugs Board, working with the Pharmacy Council, should document all imports of ARVs and available outlets in the commercial sector. A mechanism should be developed to document the dispensing and use of ARVs. NACP should use this data as a proxy measure of ARTs in the private sector and compare this with private sector provision of ARTs.

5. The MOH should take the necessary steps to include HIV/AIDS commodities on the NEDL.

Most HIV/AIDS commodities, including several ARVs, are not currently included on the NEDL. As part of the process of sensitizing health workers and the public about the availability, use, and regulation of these commodities, they should be added to the list. The MOH should initially take the steps necessary to include these commodities by using an interim supplemental list, and then add HIV/AIDS commodities officially to the NEDL at the next formal review.

6. When selecting sites to begin ART, NACP and the MOH should base the selection on the site's readiness to implement HIV/AIDS care and the extent of preparations needed.

JSI/DELIVER has developed an assessment tool to assist in selecting sites for ART. The goal of rating the Stages of Readiness is to develop a set of criteria for selecting ART sites not based on site type, but on capacity, vision, and activities needed for rational introduction and expansion of ART into HIV care. Six domains of a program are reviewed to assess site readiness: Leadership; Services; Protocols, Management, and Evaluation; Experience and Staffing; Laboratory Capacities; and Drug Management and Procurement. The evaluation of each of these criteria determines into which of the five stages a program falls. The stages rating system can be used for program start-up and expansion within the site to identify steps needed to advance a site along the stages from a *Program Mobilization* stage (Stage 1) to an *Action* rating (Stage 4) and, ultimately, *Support, Maintenance, and Expansion* (Stage 5). NACP should use the Stages of Readiness or a similar set of criteria when selecting sites for ART start-up and expansion.

7. NACP and the administration of each ART program site should identify and appoint an ART manager at each site to monitor quality and performance of the ART program during the introduction and implementation of ART services.

To ensure the success of ART in a service facility, there must be a leader committed to introducing ARVs in the site who has a vision on how it is going to be done and what assistance may be required. The leader should also determine the continuum of care, from diagnosis (VCT/PMTCT, TB, or clinical diagnosis), through management of OIs, including diagnosis and treatment of TB and ART. The leader should have experience in managing HIV-related health care programs and should be engaged in spearheading the ARV program. The leader should also have established or plans to establish linkages and advocates for capacity building of staff in HIV/AIDS care and monitoring of their performance. Linkages should also be established with NACP to ensure continuous supplies of HIV/AIDS commodities and quality control.

# Site Readiness to Provide ART

## Public Sector Facilities

### **Atua Government Hospital and St. Martin's Catholic Hospital, Manya Krobo District**

Both Atua and St. Martin's Hospitals have been rated at Stage 4: *Action* using the Stages of Readiness Assessment Tool and are ready to start ARV therapy for their eligible clinical care patients. Several recommendations have been provided at the end of this section to further prepare the sites to provide this service.

Each hospital has trained leadership (two physicians each and dedicated nursing staff) who have been fully engaged in developing the ART program and model of care. Dispensing of ARVs will be done through a modified DOT system with *drug buddies*. While some initial training has been done for clinical and pharmacy staff on ART, given the time lag between training and delivery of ARVs, refresher training will be required. Other than ART, which should be available within the next month, both facilities offer a full range of HIV/AIDS services, including VCT, PMTCT, and diagnosis and treatment of OIs, STIs, and TB. Home-based care has started on a small scale and needs to be expanded. Hospitals will soon provide CRS-donated food aid.

Both facilities have the active support of the community for all HIV services. The District Health Management and several NGOs have been involved in community mobilization, awareness raising, and prevention activities. The hospitals have an active association of PLWHAs.

Site specific ART protocols for eligibility, treatment, support, adherence, and management of side effects have been developed and are in line with national guidelines. Recording and reporting systems are in place for clinical and service information and a system for monitoring and evaluation and supervision has been developed. This will need to be fully adapted for ART. Monthly reports are prepared by each hospital. The sites have adequate staff to start ART, but some staff, particularly counseling, nursing, laboratory, and pharmacy staff, will need more training in ART support.

The hospital laboratories have the capacity to do basic tests. CD4 counts and viral load testing are currently done at Noguchi for these sites.

The hospitals have an established supply chain for most HIV/AIDS commodities with the exception of ARVs, which are not yet available. Plans are in place for direct delivery of ARVs from CMS to the sites, upon arrival in country. Other drugs are purchased on a monthly basis after approval of the hospital procurement committee. Storage facilities are adequate and have an acceptable level of security. No specific inventory control procedures are in place to ensure a continuous supply of HIV tests or NVP, though there have been no stockouts because of close monitoring and frequent resupply from the national level. No specific inventory control procedures are in place for other drugs, though initial attempts are being made to track consumption (issues from storage) and maintain a minimum stock quantity. In general, a three-month supply of drugs for treatment of STIs and OIs was available at the time of a visit, but a significant undersupply of Cipro was noted. No expired stock was noted. Stock keeping records are well kept and up-to-date. Physical inventories are taken routinely. Losses and adjustments are not recorded. Adequate transaction records are maintained to track stock movement. No record of drugs dispensed to clients is maintained at St. Martin's with the exception of

Pfizer-donated Diflucan. A prescription register is used at Atua and quantities of drugs dispensed are recorded. There is no consistent reporting of logistics data from the facilities. Funding for HIV/AIDS-related commodities is secure for the immediate future through FHI, USAID, and the Global Fund supported procurement.

### **Recommendations**

1. Complete training of clinical, nursing, counseling, pharmacy, and laboratory staff in provision of ART including management of side effects, support, and adherence. Pharmacists who will be dispensing ARVs should take an active role in adherence counseling.
2. Establish site level logistics management information system. Prescription registers should be established and maintained to record the quantities of each ART drug dispensed to patients. Similar records should be maintained for HIV tests, NVP, and drugs for treatment of OIs. A system for consistent reporting of service and logistics data should be established using standardized formats.

Logistics data reported should include the following for each HIV/AIDS commodity:

- beginning stock balance
  - receipts
  - consumption (dispensed to patients)
  - losses and adjustments (transfers to other sites, expiry, damaged commodities)
  - ending stock balance (including quantities per expiry date).
3. Establish inventory control procedures for routine monitoring of stock levels for HIV/AIDS commodities to ensure a consistent, adequate supply and account for lead times for resupply.
  4. To ensure full accountability, site and national level program managers should monitor dispensing of ARVs using routine monthly reporting to reconcile quantities dispensed against reported service data.

### **Korle Bu Teaching Hospital**

Korle Bu Teaching Hospital has been rated at Stage 4: *Action* using the Stages of Readiness Assessment Tool, and is preparing to start ARV therapy for eligible clinical care patients. Several recommendations have been provided at the end of this section to prepare to provide this service.

### **HIV/AIDS-Related Services**

The Korle-Bu Teaching Hospital currently has no comprehensive HIV/AIDS services. The treatment and care of adults with HIV/AIDS is undertaken at the fevers unit within the Department of Medicine. Patients are referred from all over the country, at least from the whole of the southern sector of Ghana, to the fevers unit. A lot of referrals are also made from other departments of the teaching hospital to this unit.

There is currently a Resident in Internal Medicine who is effectively the head of this unit and sees most of the HIV/AIDS patients referred to the unit. The role and function of this unit or individual in the hospital is not in dispute. However, this is yet to be formalized enough, to enable the needed leadership for HIV/AIDS care in the hospital.

### ***Protocols and Procedures***

The hospital is yet to adopt or adapt the existing national guidelines and protocols for the HIV/AIDS services of the hospital.

There is minimal use of ART in the hospital. It is reported that about 15 patients who can afford the open market prices are currently being treated through the fevers unit. These patients are given prescriptions, which are filled in private pharmacies in town. The current treatment of choice is a first-line of Combivir (AZT + 3TC) + efavirenz (EFV). Reports of difficulties in obtaining a supply of EFV has engendered an alternative first-line of Viracept (NFV) + Combivir in the case of a few patients. These are quite consistent with the draft national protocols. The need to have an official protocol for use in the hospital cannot be overestimated. The hospital has a post exposure prophylaxis regime and practice in place. Staff who are exposed and at risk in the line of duty are offered post exposure prophylaxis (PEP). Currently, the hospital bears the cost of the ARVs provided to these staff. There is, however, no official policy on PEP. Two trained clinicians have been designated to PEP prescribing.

VCT services are almost nonexistent in the hospital. There are currently four nurse counselors available at the fevers unit. The hospital uses these counselors mainly for pre- and post-test counseling, but not in the framework of VCT service. Officials of the hospital were quick to point out the difficulties associated with the operation of true VCT services at the fevers unit. Among the key considerations are the high levels of stigma attached to the fevers unit because it has become excessively identified with full-blown AIDS patients. The officials were also quick to mention plans to establish VCT services at an acceptable location within the hospital.

The other issue of concern in the provision of full range of care and support services for HIV/AIDS clients is the undefined limits of the *community* served by the hospital. As the country's premier tertiary referral hospital, the hospital treats patients as well as those referred from public and private facilities from all over the country. The net effect of this is the difficulty in follow-up activities after patients are discharged. While follow-up activities may not be possible for all the clients, the hospital is still the primary point of care for the neighboring communities through its polyclinic facilities. This offers an opportunity to develop linkages with and utilize community-based organizations (CBOs) in the immediate neighborhoods for home-based care and support activities.

Laboratory services that support the provision of clinical care at the teaching hospital are nearly the best in the country. The hospital is home to the NPRHL where all confirmatory tests for HIV in the country are done. The developed hematology and other laboratories are available to support diagnosis and treatment using ARVs. There are no facilities for CD4 counts and viral loads, but there are plans to upgrade and acquire the needed equipment to undertake these tests. In the interim, facilities at the NMIMR are used.

### ***Inventory Management***

The teaching hospital has a network of pharmacies in each major clinical area, supported by a central store. It also has an autonomous pharmacy within the hospital that stocks a wider range of drugs, including some OI medicines.

The hospital manages its drug supply on a full-cost recovery basis and has a sustainable supply situation. The inventory control system is computerized and a paper-based backup is maintained for stock records using stock cards and ledgers. The LMIS is composed of a set of transaction records and reports that are produced monthly at the service points and quarterly in the main stores.

### Recommendations:

1. The Teaching Hospital Korle Bu should identify and appoint an ART focal person. The person will oversee the management of clinical care of PLWHA and coordinate with the NACP.
2. The health management information system in the fevers unit needs to be improved to capture the data on AIDS patients, OIs, prophylaxis, and ART. Forms designed by the FHI Start Project in Many Krobo could be used for data collection in Korle Bu.
3. Nurses and social workers should be trained as HIV/AIDS counselors. Presently, there are four counselors at the fevers unit but 16 are required. They should also be trained, in phases, in support and adherence counseling skills. The counselors should also participate in regular meetings to exchange experiences to reduce the risk of burnout.
4. Identify and train a pharmacist to be attached to the fevers unit to manage HIV/AIDS commodities and ensure support and adherence counseling.
5. The national PEP policy should be adapted to Korle Bu. ART prescribers should be identified and workers in the institution should be informed.
6. VCT and PMTCT services should be offered by Korle Bu to respond to the need of the clients of this hospital.

### Komfo Anokye Teaching Hospital

Komfo Anokye Teaching Hospital (KATH) was rated at Stage 3: *Preparation* using the Stages of Readiness Assessment Tool. It will need to make significant improvements to its services and systems before being able to start ARV therapy for their eligible clinical care patients.

At this time, Komfo Anokye has not identified a focal person to coordinate the development of ART services at the hospital and no specific model of care has been proposed. While the clinical staff treats OIs and STIs, no ART is provided at this time and only limited HIV/AIDS-related services are available. HIV testing is available for clinical diagnosis. A counseling unit has been established but is not yet doing VCT. PMTCT has not been initiated, although a committee has been established for PMTCT and has submitted a proposal to the MOH to begin activities in this area. There is no specific identifiable space in which to offer ART. No networks have been established in the community to support expansion of HIV/AIDS services.

While Komfo Anokye has access to national protocols for ART, they have not been adapted for use at the hospital. The site has basic medical record keeping that will need to be expanded to include ART. Mechanisms for monitoring and evaluation of the ART program will have to be developed.

Clinical staff have experience in treating OIs and STIs but have had no specific training in ART. Additional staff may need to be hired and trained to provide the full spectrum of HIV/AIDS treatment and care.

Laboratory services are good. The serology lab does HIV testing with test kits supplied by the PHRL. Currently, Innostest is used as the first test, Determine is the second. Tiebreaker tests are conducted by PHRL using Inno-Lia. The lab picks up a resupply quantity of HIV tests when stock balances have reached a certain level. The lab has good internal and external quality control in place. It provides monthly reports to PHRL on the numbers of samples (patient and donors) screened and the number testing positive. The lab technician reported that the types of test kits change often, which causes

problems because all three technicians may not know how to use the different tests. CD4 and viral load testing is referred to Medlab.

Information on the type and quantity of drugs dispensed to patients is currently recorded but is not aggregated for use in procurement or management of drugs. Stock keeping records are generally well kept. Appropriate transaction records are used. Storage of drugs in the hospital stores can be improved. While, in general, shelving is available for many commodities, there is inadequate space to properly store all drugs. In some cases, cartons are placed directly on the floor or stacked too high. Large quantities of expired stocks occupy valuable storage space while awaiting authority for disposal.

Drugs and lab supplies are procured quarterly based on annual estimates of needs. The hospital procurement committee can authorize purchase of additional drugs and supplies during their monthly meetings. The stores managers try to keep a minimum stock level for all supplies.

### ***Recommendations***

1. Identify someone to lead the ART program initiation and expansion at KATH.
2. Develop a strategic framework and implementation plan to prepare KATH to provide ART, to include—
  - Establish other HIV services according to national guidelines, specifically VCT and PMTCT.
  - Train clinical, nursing, and pharmacy staff in ART and adherence counseling.
  - Determine the model of care that will be used and develop formal clinic-specific written protocols for eligibility, regimens, initiation, clinical and lab monitoring and follow-up, adherence, management of side effects, and treatment interruption and treatment failure.
  - Identify the physical location and space that will be used for clinical care and ART.
  - Identify ART indicators and an appropriate system for monitoring ART activities.
3. Establish a site level LMIS.

Prescription registers should be established and maintained to record the quantities of each ART drug dispensed to patients. Similar records should be maintained for HIV tests, NVP, and drugs for treatment of OIs. A system for consistent reporting of service and logistics data should be established using standardized formats. Logistics data reported should include the following for each HIV/AIDS commodity:

- beginning stock balance
  - receipts
  - consumption (dispensed to patients)
  - losses and adjustments (transfers to other sites, expiry, damaged commodities)
  - ending stock balance (including quantities per expiry date).
4. Establish inventory control procedures for routine monitoring of stock levels for HIV/AIDS commodities to ensure a consistent, adequate supply, and account for lead times for resupply.

## Private Sector Facilities

### Akai House Clinic

Akai House Clinic is rated at Stage 4: *Action* using the Stages of Readiness Assessment Tool, and is ready to expand its provision of ARV therapy for its eligible clinical care patients.

Akai House Clinic is a private health facility working with PAI and CMS to expand its HIV/AIDS-related services, including clinical care involving provision of ART. Akai House Clinic is currently managing eight patients on ART using Combivir and efavirenz as first-line drugs. This protocol is in line with the current MOH/GHS treatment protocols. They hope to expand the number of patients on ART by about 4–5 per month over the next year.

Akai House Clinic has identified leadership to manage the expansion of ART. It has four physicians, several nurses, one full-time VCT counselor, and another counselor soon joining the staff. They are also planning to hire a dispensing technician. The clinic offers VCT, treatment for OIs and STIs, and TB diagnosis. Treatment for TB is referred to La Polyclinic. PMTCT is not yet underway, but will be made available.

ART protocols and model of care are under development with assistance from PAI. PAI will also provide ART training for two of the clinic physicians, and CMS will provide additional training for counselors.

The clinic has good record keeping capacity to monitor patient treatment and care. PAI will provide ART-specific software to the clinic for client and treatment management, and they have a *hotline* available to the physicians for assistance with case management. They will also establish a system for regular case review.

Akai House Clinic uses Medlab for its laboratory tests. Medlab is a state-of-the-art facility with good internal and external (international) quality monitoring. Medlab currently sends samples for CD4, viral load, and PCR to South Africa for testing, at a cost of about \$140 to the client for CD4 and viral load. It expects to have on-site CD4 capacity in a few weeks and viral load testing by the end of the year, which should bring the patient cost down. The lab has a computerized inventory control system and uses maximum-minimum (max-min) stock levels to facilitate ordering.

Akai House Clinic procures its drugs through local drug wholesalers and receives them within 24 to 48 hours after ordering. A patient prescription register tracks quantities of drugs dispensed and produces a monthly stock position report. The nurse in charge is responsible for determining resupply quantities of drugs, which are managed using a max-min inventory control procedure. Some expiry has been experienced with specialty drugs and drugs received by donation. Patients pay for ARVs, which are marked up 5–1 percent over the clinic's purchase price. The clinic is currently covering the cost of drugs for a few patients who are unable to pay for them.

### Recommendations

1. Complete development of formal clinic specific written protocols for eligibility, regimens, initiation, clinical and lab monitoring and follow-up, adherence, management of side effects, and treatment interruption and treatment failure.
2. Develop ART indicators and appropriate system for monitoring ART activities.

3. Develop a formal plan for expanding ARVs at the clinic. Expand scope to include PMTCT and increase ART capacity of staff through additional training of physicians and counselors.
4. To ensure continued access of ARVs to eligible clinical care patients, negotiate the lowest prices available from drug sellers. Explore the possibility of purchase of ARVs from MOH/GHS to benefit from lower cost international procurement prices and pass these savings on to the patients.

## Nyaho Medical Center

The Nyaho Medical Center is a 32-bed private facility providing comprehensive and integrated health care services. The facility, established in 1970, has a good track record and reputation for providing premier services to a select community in Accra. The facility also has a group medical practice that attracts a number of specialists in various fields from the Korle-Bu Teaching Hospital. The medical center currently has five full-time general practitioners and 38 specialist consultants delivering services through its facility. The medical center has in-house laboratory and pharmacy services.

Nyaho Medical Center is rated at Stage 4: *Action* using the Stages of Readiness Assessment Tool, and is ready to initiate and expand its provision of ART for its eligible clinical care patients.

Services at the center are integrated. The same wards are used for practically all services. The center collaborates with the Chest Clinic of Korle-Bu Teaching Hospital, with the latter providing drug supplies for TB patients.

It was unable to establish if the facility currently has an ART program; however, given the close relationship of the facility with specialist consultants from the Department of Medicine of the Korle-Bu teaching hospital, it is safe to assume that patients who can afford the drugs are put on ART. Nyaho Medical Center is working with PAI and CMS to implement and expand its HIV/AIDS-related services, including clinical care involving provision of ART. Under this initiative, the Nyaho medical center has identified three nurses to be trained as counselors and two doctors for training in ART. The center has already provided some sensitization and training for staff on attitude change in handling patients to reduce stigma.

ART protocols and model of care is under development with assistance from PAI. PAI will also provide ART training for the selected physicians and provide additional training for counselors.

Counseling for HIV testing is provided currently by two physicians, and the center uses Medlab for its HIV tests. Medlab is a state-of-the-art facility with good internal and external (international) quality monitoring. Medlab currently sends samples for CD4, viral load, and PCR to South Africa for testing at a cost of about \$140 to the client for CD4 and viral load. It expects to have on site CD4 capacity in a few weeks and viral load testing by the end of the year, which should bring the patient cost down. The lab has a computerized inventory control system and uses max-min stock levels to facilitate ordering. Other lab services are provided in-house at Nyaho, and Medlab provides a back up, should the need arise. Hematology and chemistries are conducted using modern auto-analyzers.

Drug procurement is through local drug wholesalers, and the clinic receives the drugs within 24 to 48 hours after ordering. Pharmacy record keeping is automated. The software is used to track quantities of drugs dispensed and a monthly stock position report is produced. The hospital has two pharmacists responsible for determining resupply quantities of drugs, which are managed using a max-min inventory control procedure.

The medical center has selected the following treatment protocol:

*First-line:* Combivir, efavirenz, Viramune

*Second-line:* stavudine, DDI, Kaletra

*PMTCT:* Combivir, Viramune tab, Viramune susp

*PEP:* Combivir, Kaletra

Kaletra is not currently registered in Ghana.

Clinical records management is at a very basic level. Patient information and clinical notes are kept in patient folders and there are no records maintained on daily summaries of attendance and diagnosis. While it is possible to obtain total daily attendance, it is not possible to determine summaries of the conditions presented.

### **Recommendations**

1. Complete development of formal clinic-specific written protocols for eligibility, regimens, initiation, clinical and lab monitoring and follow-up, adherence, management of side effects, and treatment interruption and treatment failure.
2. Develop ART indicators and appropriate system for monitoring ART activities. There is a need to develop a system of reporting ART activities to the NACP, and to monitor patient responses with a view to developing an appropriate database to support future changes in treatment protocols and policies.
3. Expand scope to include PMTCT, VCT, and increase ART capacity of staff through additional training of physicians and counselors. There is also the need to establish a clear policy and framework for PEP in the center.
4. Ensure the continued access of ARVs to eligible clinical care patients, and negotiate the lowest prices available from drug sellers. Explore the possibility of purchase of ARVs from MOH/GHS to benefit from lower cost international procurement prices and pass these savings on to the patients.
5. Revise treatment protocols to include only those drugs that are registered and, therefore, available in Ghana.

### **Holy Trinity Hospital**

Holy Trinity Hospital is a 30-bed facility established in 1988. The hospital provides a range of integrated health care services, and is located in a relatively densely populated area of Accra. The facility also has a group medical practice and attracts a number of specialists in various fields. The hospital has a team of 28 doctors including specialists in eye, dermatology, surgery, gynecology, dietetics, and psychiatry, among others. The group practice minimizes referral to the teaching hospital and facilitates a regular exchange of contemporary medical knowledge, practice, and research. Additional services include laboratory, x-ray, and pharmacy. The hospital sees a daily average of between 350 and 500 patients.

Holy Trinity Hospital is rated at Stage 4: *Action* using the Stages of Readiness Assessment Tool and is ready to initiate and expand its provision of ART for its eligible clinical care patients.

The hospital collaborates with the Chest Clinic of Korle-Bu Teaching Hospital for the treatment of TB patients and has set up a DOTS location at its premises with adequate seclusion to ensure confidentiality of patients as they come in to take their medication, with supervision. The hospital receives anti-TB drugs from the National TB control program and has participated in training programs offered by the TB program.

The hospital does not currently have an ART program, but refers all patients who test positive for HIV to the Korle-Bu fevers unit for continued management. Holy Trinity Hospital is working with PAI and CMS to implement and expand its HIV/AIDS-related services, including clinical care involving provision of ART. Under this initiative, Holy Trinity Hospital has identified nurses to be trained as counselors and three doctors for training in ART. The hospital is just about to take a team of doctors and other health workers on a trip to the USA to observe the treatment and care of HIV/AIDS patients in New York, Baltimore, and Washington, D.C. The hospital's short-term plans include the recruitment of clinical psychologists to be trained and used for HIV and other medical counseling services. The hospital provides immigration medical screening for the U.S. Embassy and conducts HIV testing on-site.

ART protocols and model of care is under development with assistance from PAI. PAI will also provide ART training for the selected physicians and counselors.

Laboratory services at the hospital are highly advanced. HIV testing is done by ELISAs for both the primary screening and the confirmatory tests. The hospital has a good quality assurance system and uses the services of the Centers for Disease Control and Prevention (CDC) for its external quality assurance.

Drug procurement is through local drug wholesalers, and the hospital receives the drugs within 24 to 48 hours after ordering. Pharmacy record keeping is automated. Software is used to track quantities of drugs dispensed and a monthly stock position report is produced. The hospital has two pharmacists responsible for determining resupply quantities of drugs, which are managed using a max-min inventory control procedure. A module of the software that is used for stock and inventory management is also used to manage patient records and accounting. This integrated software enables easy data access and appropriate reports to be generated at each level. Even though a thorough assessment of this software was not conducted, it looked impressive at first glance.

### ***Recommendations***

1. Complete development of formal clinic specific written protocols for eligibility, regimens, initiation, clinical and lab monitoring and follow-up, adherence, management of side effects, and treatment interruption and treatment failure.
2. Develop ART indicators and appropriate system for monitoring ART activities.
3. Expand scope to include PMTCT and increase ART capacity of staff through additional training of physicians and counselors.
4. Ensure the continued access of ARVs to eligible clinical care patients, negotiate the lowest prices available from drug sellers. Explore the possibility of purchasing ARVs from MOH/GHS to benefit from lower cost international procurement prices and pass these savings on to the patients.

## **Ashanti Goldfields Company Limited Hospital**

The Ashanti Goldfields Hospital is located in Obuasi about 80 km south of Kumasi. The company serves mine workers of two companies MBC (7,536 subjects) and AGC (7,143 subjects), their dependents, and surrounding villages. There are five physicians, two specialists, and three medical officers.

Ashanti Goldfields Company Hospital is rated at Stage 3: *Preparation* using the Stages of Readiness Assessment Tool and the hospital will need to make significant improvements to its services and systems before being able to start ARV therapy for their eligible clinical care patients.

### ***HIV/AIDS Related Services***

AGC Hospital offers a number of HIV-related services to the population of its catchment area.

There is an ongoing campaign to promote condom use in the AGC Hospital catchment area and other education messages on the prevention of HIV transmission. Many billboards with HIV/AIDS messages are widely distributed in and around Obuasi.

Clinical patients suspected of HIV-related illnesses are counseled (pre-test and post-test counseling) but there is no walk-in VCT. Serial testing protocol is applied: ELISA is the screening test, reactive sample, and tested with a supplementary rapid test (HIVSpot). For discordant results, there is apparently no tiebreaker protocol. There are five trained HIV/AIDS counselors at AGC Hospital.

AGC Hospital is among the six PMTCT centers that will be sponsored by the EU through Noguchi Memorial Institute of Medical Research. The training of counselors will be conducted during the weeks of April 23 and May 2, 2003. Two weeks prior to the date of our visit (April 15, 2003), CARE International had conducted a course on counseling in which AGC Hospital participated.

Management of OIs and STIs is integrated in the clinical service to patients on a daily basis. The syndromic approach is implemented according to the national protocols.

Tuberculosis has been an important public health problem among miners for more than a decade. In the past, miners presenting with symptoms and signs of TB were referred to KATH. It was remarked that most of the miners were on an indefinitely long treatment protocol. An assessment of the situation was made and it was decided that clinicians would be trained to manage TB patients, using the national TB control program guidelines. Thus, patients were treated at AGC Hospital with spectacular outcome. The DOTS was implemented, which indicates there is good community linkage with outreach activities under the leadership of a public health nurse. Experience from the TB program at AGC could be very helpful in the eventual implementation of the ART/DOT, if the hospital chooses to implement this strategy.

Even though there is no ART program in AGC Hospital, as yet, this institution has shown interest in eventually providing ARVs to the miners living with HIV/AIDS in Obuasi. Contact has been made with CMS but a contract has not been signed.

**Laboratory Support Services:** AGC Hospital has the capacity to perform tests required to implement ART except CD4 cell counts and viral load, but linkage with Medlab or Noguchi could be established.

***Protocols and Procedures***

The current activities in the areas of STIs, OIs, and TB are based on the national guidelines and protocols. The hospital has not necessarily adapted the protocols and guidelines for its own operations. All treatment in AGC Hospital is free of charge for patients.

***Inventory Management***

Logistics data are captured by automated system.

**Challenges:**

- Maintaining a regular supply of ARVs.
- Expected high cost to the company (miners and dependents).
- Monitoring of side effects and treatment failures, including CD4 and VL.

**Recommendations:**

1. Identify a focal person to lead the ART program in initiation and expansion at AGC.
2. The leader should have defined goals and vision and be more incorporated into day-to-day activities and future plans. She or he should assist with designing an ACG ART program, including definition of model, staffing plan, and site spectrum of care.
3. Complete development of formal clinic-specific written protocols for eligibility regimens: initiation, laboratory monitoring and follow-up, adherence, management of side effects, and treatment interruption and treatment failure.
4. Complete training of clinical nursing, nursing, counseling, and pharmacy and laboratory staff in provision of ART including management of side effects, support, and adherence.
5. Complete arrangement with CMS for contractual agreement for introducing and expanding ART in the ACG Hospital.
6. Establish inventory control procedure for routine monitoring of stock levels for HIV/AIDS commodities to ensure consistent supply and accounting for lead time for resupply.



# Annexes

1. Central Level Questionnaire
2. Facility Logistics Management Questionnaire
3. Facility Services and Infrastructure Questionnaire.
4. Stages of Readiness Assessment Tool: To Evaluate Site Readiness for Antiretroviral Therapy (ART) Introduction
5. List of Persons Contacted
6. Antiretroviral Drugs Registered by the Food and Drug Board in Ghana
7. Antiretroviral Therapy Treatment Protocols
8. HIV Tests and Testing Protocol in Ghana



## **Annex 1**

# **Central Level Questions**



# Central Level Questions

Goal is to assess the capacity and level of readiness on national and site-specific levels for the use of ARV's in the context of a secure supply chain. There are two parts to this questionnaire. The central level questionnaire will address questions from a policy/protocol/guidelines perspective. Site specific questionnaire will address the readiness of a specific site to begin to use ARVs.

Questions are based in part on UNAIDS/WHO Scaling up ARV therapy in resource-limited settings, the draft guidelines for Antiretroviral Therapy in Ghana of March 2002, and other sources. They are based on the concept that ARV supply chain logistics ends with the consumer, and so capacity and readiness through identification and care is essential for this assessment.

If no policy/plan is existing ask about plans to develop (including people/resources and agencies involved), if available (even in draft) request a copy.

Date:

Persons participating in interview:

Interviewers:

## **General:**

1. Does an ART program exist in Ghana? Yes or No
2. If yes, who sets policy and procedures used in the program?
3. What are the sources of funding for the ART program?
4. Are there funds committed for
  - a. Human resources
  - b. Procurement of commodities
5. Do you plan to produce ARVs in Ghana?

## **Financing:**

1. Will patients pay for ARVs and HIV-related illnesses? Yes or No
2. If not, what level of subsidy will be provided?
3. Would the subsidy be part of the national health insurance scheme? Yes or No
4. If yes, how will the subsidy be financed?
5. Will all OIs be included?
6. What is the cost of ARVs per patient per month?
7. Does the program plan to treat children?
8. What cost-recovery options do you plan to implement in the ART program?
9. Does the Ministry of Health have a budget line for ARVs? Yes or No.
10. If not, are there any plans?
11. Have any committed external funding been so far secured in support of this program? Yes or No.
12. If so, who are the donors?
  - a. Global Fund
  - b. USAID
  - c. Loans
  - d. Donations
  - e. Other, specify\_\_\_\_\_

## **VCT:**

1. Are there any guidelines and protocols for VCT? Yes or No. If yes, could I kindly have a copy?

2. Are there any facilities for testing for HIV in a VCT setting?
3. Where are they located?
4. What types of counselors does the VCT program have?
  - a. nurses
  - b. social workers
  - c. other health providers
  - d. lay counselors/PLWH/A
  - e. other, specify \_\_\_\_\_
5. What is the projected need for the future for counselors? (Minimum number of counselors per site with respect to the workload: what is the expected number of clients that a counselor can counsel per day? Are these full-time or part-time counselors? In which setting?)
6. Does the expansion plan take into account regional, district, urban and rural distribution?
7. Which HIV tests have been approved for VCT use?
8. Which type of HIV testing protocols are used?
9. Is there any payment for VCT services?

## **National PMTCT policy and plan:**

1. Do all ANC attendees receive information on VCT?
2. Are PMTCT services offered in Ghana? Yes or No.
3. If so, at which sites?
4. Are there plans to expand?
5. Is there any payment for deliveries for clients in a PMTCT program? Yes or No
6. Is there a national policy for feeding infants borne to HIV-positive mothers?
7. Do you provide formula to HIV-positive mothers?
8. What is the policy for diagnosis of HIV among children?

## **Capacity and training of health care workers:**

1. Do you have a policy on ARV prescription? Yes or No.
2. If yes, what are the requirements?
3. If not, do you have any plan?
4. Do you have any plans for human resources capacity building?

- a. In-services training
- b. Through curriculum development in pre-service training institutions?

## **Community involvement:**

1. What are current efforts and future plans for community involvement and mobilization to support appropriate ARV use?
  - Could you give any examples?

## **Post exposure prophylaxis (PEP):**

1. Is there a policy for occupational PEP? Yes or No.
2. If not, are there any plans?
3. Are there any ARVs in health facilities reserved for use by health workers accidentally exposed to HIV? Yes or No.
4. If not, what provisions are there for PEP?
5. To what scale is PEP implemented?

## **Research:**

1. What research around ARVs was conducted or is ongoing in Ghana (including PMTCT)?
2. What research efforts in HIV care and treatment are ongoing or planned in Ghana?
3. Who are the key internal and external partners?

## **Guidelines for ARVs:**

1. What national guidelines are in use or development for ARV use including when to start, regimens, monitoring, QA/QC and other site requirements? (including clinical trials, pilot projects, and national ART program).
2. What will be the role of the private sector (practitioners)? What type of collaboration is planned/desired/expected? What role will CMS/Pharm Access International Clinics play in provision of ART to/in the private sector?

## **Adherence support and patient education:**

1. What are national policies/plans for adherence support, role of DOT and patient education?
2. What is the current human resources capacity?
3. Are there any plans for expansion?

## Forecasting of ARV drug requirements:

1. Who is/will be responsible for preparing the forecasts for Ghana ART program?
2. How are forecasts of ARV requirements currently developed for this program?
3. How will forecasts for (a) OI medications and ARV drugs be adjusted to account for program expansion? (b) Adjustments in treatment regimens due to toxicity and drug resistance?
4. What is the current procedure for submitting commodity forecasts and requests for donor procurement? Will the same procedure be followed for OI medication and ARV drugs? If not, how will it be different? (Interviewer to verify procedures re: review/approval and timing of submission of forecasts and requests).

## Procurement planning/delivery:

1. Are all OI medications and ARV drugs on the National Essential Drugs List?
2. Are all OI medications and ARV drugs registered for use in the country by the National Drug Regulatory Authority?
3. Who is/will be responsible for procurement planning, ordering and scheduling of shipments of OI and ARV drugs?
4. Describe the procedures and timeframes for ordering products from suppliers/ donors? *(Interviewer verify if procurement plans are based on forecasted needs and if take into account current inventory levels, losses/adjustments, order lead times of donor/suppliers, and shipment and handling schedules.)*
5. What are order lead times and supplier lead times if known?
6. Are procurements limited to pre-qualified suppliers for all ART products?
7. What quality assurance procedures exist to ensure that products received meet defined standards of quality? *(Interviewer to verify who is responsible and when/how often these procedures are conducted. Is there a documented procedure for reporting complaints re: product quality to suppliers?)*
8. Describe the coordination between person(s) or unit(s) responsible for procurement and those responsible for in-country reception and distribution of ARV drugs.

## Reception and distribution:

1. Who will be responsible for in-country reception, inspection and verification of ARVs?
2. Who will be responsible for compliance with national drug regulatory authority and customs clearance requirements? (e.g. notification of arrival of consignment to port/customs authority, supplier documentation of quality testing, certificates of donation).
3. What security measures are followed to ensure the security of shipments ARV drugs through reception, transport and storage?
4. How will costs for customs clearance, storage and transport of ARVs?

## **Laboratory support:**

1. What is the policy regarding minimum laboratory testing services required to support ART in Ghana (from interviews and protocols)?
2. Are laboratory testing protocols and procedures in place for HIV testing? Is a copy available? When were the protocols updated?
3. Are laboratory technicians familiar with, or have they been trained in use of the laboratory equipment and diagnostic agents required for HIV testing? At what level?
4. How many laboratory technicians are trained to provide these services?
5. What types of training are required to provide these services?
6. How is this training currently being provided?
7. What are future needs and plans?
8. Who are the key partners supporting laboratory services?
9. Who will supervise trained laboratory technicians? At what frequency?
10. Will counselors be trained to perform rapid HIV tests?
11. What is the attrition rate of trained lab technicians and plans for retention?
12. What are the laboratory testing services currently available and being provided to support ART? What is their capacity in terms of volume?
  - Public Sector
  - Private Sector
  - Research and clinical (and overlap)?
  - What are the capacities at these sites?
  - Where are they located?
  - How long have they been operational?
  - What are the costs associated with each?
  - Is there any cost sharing arrangement?
13. Which of the following test will be required for ART Program implementation? See next page.
14. What is the expected need for laboratory scale up to support the expansion of ART?
15. What standards of certification of lab equipment and performance are in use?
16. Who is responsible for monitoring the quality of laboratory services?
17. What have been the results of any large scale QA in the last 12 months?
18. What are the issues related to equipment maintenance and repair? What are current and future needs?

19. What are the sources of supply for ART laboratory testing supplies?
20. How is procurement of these diagnostic agents and supplies financed?
21. Who procures them and how?
22. What are plans for immediate, medium term and long term funding and supply of laboratory testing equipment and supplies to support ART?
23. What are current and projected needs for these supplies (i.e. what are actual quantities of HIV testing and ART laboratory supplies currently needed and if ART is introduced/expanded, how will supply needs be forecasted?)?
24. Who calculates this and how?
25. What is current average consumption of lab supplies for testing at ART sites?
26. What are current stock levels of required laboratory supplies at ART sites?
27. How are these lab supplies ordered and re-supplied?
28. What are the record keeping and lab supply monitoring systems in place?
29. Is there an established laboratory supply inventory control system?
30. Can we get copies of any laboratory forms in use?
31. What security issues, if any, exist for storage, distribution and use of ART laboratory testing equipment and supplies?

**Laboratory form**

Test performed on site		Client cost per test	Staff trained in the last 2 years	Equipment available today?	Reagents available today?	Is there a register for results to be recorded?	Comments
	Y/N		Y/N	Y/N	Y/N	Y/N	
HIV test							
HIV diagnosis (Ab) for children ≥ 18 months							
TB –AFB in sputum							
RPR/TPHA							
VDRL							
HbsAg							
Phlebotomy							
White blood cell count							
Absolute/Total lymphocyte count							
Hemoglobin							
Hematocrit							
Liver function tests (enzymes)							
Viral load							
CD4+ cell count							
Polymerase chain reaction (PCR)							
<ul style="list-style-type: none"> <li>• Research</li> <li>• HIV Dx for children</li> </ul>							
Urea							
Bilirubin							
Creatinine							
Electrolytes							
Cholesterol and lipids							
Fasting blood sugar							
OI-related lab: PCP							
Cryptococcal diagnosis							
Urinalysis							
Screening for STI							
Pregnancy test							

## **Annex 2**

# **Facility Logistics Management Questionnaire**



# Facility Logistics Management Questionnaire

FACILITY IDENTIFICATION																									
Name of the facility_____																									
Facility location_____																									
District _____	DISTRICT..... <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td></tr></table>																								
Sub-district _____	SUB-DISTRICT..... <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td></tr></table>																								
Code of the facility	FACILITY CODE..... <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td></tr></table>																								
Facility Type: (1 = Referral hospital; 2 = District hospital; 3= Health center IV; 4 = Health center III; 5 = Health center II; 6 = District warehouse; 7=Other _____)	FACILITY TYPE <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td></tr></table>																								
Operating Authority: 1= government; 2 = non-governmental 6= Other _____)	OPERATING AUTHORITY <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td></tr></table>																								
A= Pharmacy, B= Laboratory																									
Facility characteristics: (1 = urban; 2 = rural)	URBAN/RURAL..... <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td></tr></table>																								
(1 = warehouse; 2 = SDP)	WAREHOUSE/SDP..... <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td></tr></table>																								
INFORMATION ABOUT INTERVIEW																									
Date: _____	<table border="1"> <thead> <tr> <th colspan="2">DAY/</th> <th colspan="2">MONTH/</th> <th colspan="4">YEAR</th> </tr> </thead> <tbody> <tr> <td><table border="1"><tr><td></td></tr></table></td> <td><table border="1"><tr><td></td></tr></table></td> <td><table border="1"><tr><td></td></tr></table></td> <td><table border="1"><tr><td></td></tr></table></td> <td><table border="1"><tr><td></td></tr></table></td> <td><table border="1"><tr><td></td></tr></table></td> <td><table border="1"><tr><td></td></tr></table></td> <td><table border="1"><tr><td></td></tr></table></td> </tr> </tbody> </table>	DAY/		MONTH/		YEAR				<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>	
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Interviewer(s) _____ _____ _____																									

YOU WILL WANT TO VISIT THE WAREHOUSE, STOREROOM OR STORAGE AREA WHERE THE HEALTH COMMODITIES LISTED BELOW ARE MANAGED AND ASK TO SPEAK WITH THE PERSON RESPONSIBLE FOR PHARMACEUTICALS. HIV tests

1. _____	STI drugs:
2. _____	19. Ciprofloxacin/Cipro
3. _____	20. Benzathine penicillin
4. _____	21. Doxycycline
5. _____	22. Metronidazole/Flagyl
6. _____	ARV: NVP, NVP syrup
7. _____	23. _____
	24. _____
Contraceptives:	25. _____
8. Microgynon oral pill	26. _____
9. Male condom	
10. Female condom	TB medications:
11. Depo-Provera	27. Blister pack, 1 <sup>st</sup> treatment
12. _____	28. Ethambutol
	29. Isoniazide
Opportunistic infection drugs:	30. Rifampicin
13. Fluconazole/Diflucan	31. Streptomycin
14. Cotrimoxazole/Seprin	32. Pyrazinamide
15. Aciclovir/Zovirax/Cyclovax	
16. Ketoconazole	Other Commodities:
17. ORS	33. Unused sharps containers
18. Sulfadiazine pyrimethamine	34. Syringes
	35. Disposable pipettes/Disposable tips for pipettes

Ask to talk with the pharmacy stock manager.

Introduce all team members and ask facility representatives to introduce themselves.

Explain the objectives of this survey:

Our visit is part of a logistics assessment funded by USAID to assist MOH/GHS in Ghana to establish an efficient and effective logistics management system to support ART services including ARVs, HIV tests, and related laboratory commodities.

Before providing the commodities, important program guidance must be in place. Some members of our assessment team are meeting with facility staff to inquire about policies and protocols in place for the future implementation of an ART program.

The objectives of the logistics questionnaire are to:

- Collect current information on logistics system performance and stock status of ARVs and/or key health commodities that will be required to support an ART program.
- Collect information on the training of staff who manage the logistics of these commodities.

The results of this assessment will provide the MOH and donors information about the steps that need to be taken before providing antiretroviral therapy and introducing ARV drugs into the health system.

We would like to ask you a few questions about the logistics procedures and the commodities and supplies available at this facility, and then we will be asking to see some of the places, or items that we have asked about. Do you have any questions?

Respondents interviewed at this site:

Title                      Length in current position                      \*\*Received training in logistics?  
(If yes, specify product categories & dates)

a. \_\_\_\_\_ years/months \_\_\_\_\_

b. \_\_\_\_\_ years/months \_\_\_\_\_

c. \_\_\_\_\_ years/months \_\_\_\_\_

d. \_\_\_\_\_ years/months \_\_\_\_\_

e. \_\_\_\_\_ years/months \_\_\_\_\_

f. \_\_\_\_\_ years/months \_\_\_\_\_

g. \_\_\_\_\_ years/months \_\_\_\_\_

\*\* Explain that when we speak of logistics we are talking about the management of the health commodities products, drugs and other supplies that are used to treat the clients. Logistics includes ordering and receiving supplies, inventory management, and supervision. If speaking to the person in charge of TB, ask specifically “Have you received formal training for TB drug logistics management?”

401	Do you <u>have</u> the following logistics forms currently available to manage health products? IF “NOT AVAILABLE” TO BOTH A AND B, THEN SKIP TO QUESTION 409	OBSERVED	REPORTED AVAILABLE	NOT AVAILABLE
	Stock cards/records	1	2	3
	B. LMIS form(s) (must include requisition and issue vouchers, tally sheets, etc.)	1	2	3

NO.	QUESTIONS	CODE CLASSIFICATION	GO TO
402	Do you <u>use</u> the following logistics forms to manage health products?		
	Stock cards/records	YES .....1 NO .....2	IF NO TO BOTH A AND B, THEN SKIP TO QUESTION 406
	B. LMIS form(s) (must include requisition and issue vouchers, tally sheets, etc.)	YES .....1 NO .....2	
403	How is the information on these forms used? CIRCLE ALL THAT APPLY	Calculating consumption.....A Calculating needs .....B Reporting use to the higher level.....C Requesting supplies from the higher level.....D Other, .....W	

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NO.	QUESTIONS	CODE CLASSIFICATION	GO TO
404	If LMIS forms are used, are reports sent to the higher level?	YES .....1 NO .....2 NOT APPLICABLE .....3 DON'T KNOW .....8	→407 →407
405	How often are these transaction reports sent to the higher level?	Monthly .....A Quarterly .....B Semi-annually .....C Annually .....D Not Applicable .....E Other, .....W	
406	How often are you supposed to send these reports to the higher level?	Monthly ..... 1 Quarterly .....2 Semi-annually .....3 Annually .....4 Not Applicable .....5 Other, .....6	
407	How many facilities should send reports to this facility?	If not applicable .....NA <input type="text"/> <input type="text"/> <input type="text"/>	IF ZERO →409
408	Provide an approximate number of facilities that send these reports according to schedule.	If not applicable .....NA <input type="text"/> <input type="text"/> <input type="text"/>	
409	How many times have you placed an order or submitted a procurement request in the last year?	Never .....1 0-3 times a year .....2 4-6 times a year .....3 more than 6 times a year .....4 None .....5	
410	How often are you supposed to place orders or submit a procurement request? CIRCLE ALL THAT APPLY  Comment	Monthly .....A Quarterly .....B Semi-annually .....C Annually .....D Not Applicable .....E Other, .....W	
411	Who determines this facility's re-supply quantities? CIRCLE ALL THAT APPLY  Comment	The facility itself (pull) .....A The facility at the higher level (push/topping up) .....B Other, .....W	

NO.	QUESTIONS	CODE CLASSIFICATION	GO TO
412	How are the facility's re-supply quantities determined?  Comment TB supply	Formula (DESCRIBE IN COMMENT SPACE) .....1 Higher level facility determines .....2 Other means, .....8	
413	Which data elements are used to calculate the facility's re-supply quantities? CIRCLE ALL THAT APPLY	Beginning of reporting period stock level .....A End of reporting period stock level .....B Quantity received .....C Quantity dispensed .....D Losses and adjustments .....E Other, .....W	
414	How did you learn how to complete the forms used at this facility? CIRCLE ALL THAT APPLY	During a logistics training .....A On the job training .....B On the job (self-learning).....C Other, .....W	
415	Who is responsible for transporting commodities to your facility? CIRCLE ALL THAT APPLY	This facility collects .....A Higher level facility.....B Supplier delivers.....C Other .....W	
416	What mode of transportation is most often used? CIRCLE ALL THAT APPLY	Public transportation .....A Facility-managed vehicle .....B Private, hired vehicle .....C On foot .....D Other .....W	
417	Do you conduct supervisory visits? If no, go to 418	Yes .....A No .....B	
418	How often are you supposed to conduct supervisory visits?	Monthly .....1 Quarterly .....2 Biannually .....3 Annually .....4	
419	When did you conduct your last support supervisory visit?	Within the last month .....1 Within the last 3 months.....2 Within the last 6 months.....3 Never .....4 Not Applicable .....5 Other .....6	
420	When did you receive your last support supervisory visit?	Within the last month .....1 Within the last 3 months.....2 Within the last 6 months.....3 Never .....4 Not Applicable .....5 Other .....6	→421 →421

## Ghana: Preparing for the Management of Antiretroviral Drugs

NO.	QUESTIONS	CODE CLASSIFICATION	GO TO
421	Who conducted the last support supervisory visit that you received? SPECIFY POSITION OF THE PERSON	_____	
422	What was done during the supervisory visit you received? (Circle all that apply)	Supplies checked.....A Stock cards checked .....B Expired stock removed.....C LMIS reports checked.....D On the job training/coaching .....E Other _____ W	

FIRST CHECK FOR THE COMMODITIES BELOW TO CHECK SIMPLY FOR PRESENCE OF AT LEAST ONE USABLE UNIT.

			Observed	Reported Available	Not Available
423	Unused sharps boxes	One box	1	2	3
424	Disposable pipettes/disposable tips for pipettes	One full box (of either one)	1	2	3

## 423. Stock Status Table (April 2002–March 2003)

- In column 9, enter the total amount of expired quantities of products that are on the shelf or anywhere inside the storeroom for each product.

Product	Units of Count	Product managed by this facility? Y/N	Total consumption or issues (April 2002–March 2003)	Out of these 12 mos, no. of mos. of data available	Usable stock on hand		Has order been placed? Y/N	Expired products
					From physical inventory	From stock ledger or stock cards		
1	2	3	4	5	6	7	8	9
Multispot	Tests							
Unigold	Tests							
Lofem	Cycle							
Male condom	Piece							
Female condom	Piece							
Depo-Provera	Vial							
Fluconazole/ Diflucan	150mg cap							
Cotrimoxazole/ Septrin	400/80mg tab							
Chloroquine	Adult tab							
Sulphadox. Pyrethamine/ Fansidar	500 mg/25 mg tab							
Ciprofloxacin/Cipro	500 mg tab							

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Product	Units of Count	Product managed by this facility? Y/N	Total consumption or issues (April 2002-March 2003)	Out of these 12 mos, no. of mos. of data available	Usable stock on hand		Has order been placed? Y/N	Expired products
					From physical inventory	From stock ledger or stock cards		
1	2	3	4	5	6	7	8	9
Benzathine penicillan	2.4 mu powder							
Doxycycline	100 mg tab							
Metronidazole/ Flagyl	200 mg tab							
Nevirapine	200 mg tab							
Nevirapine	50mg/ml (240ml)Syr up							
Stavudine	30 mg							
Blister pack: 1 <sup>st</sup> TB treatmt	Pack							
Ethambutol	400 mg tab							
Isoniazide	100mg tab							
Rifampicin	150 mg tab							
Streptomycin	Vial 1000mg							
Pyrazinamide	500 mg							

## 424. Stockout assessment table (April 2002–March 2003)

Review the stock cards from **April 2002 – July 2003** to identify if any products stocked out. Alternatively, ask knowledgeable staff to identify if any products have stocked out during this period.

For all products that are both checked as products managed by this facility and had a stockout between April 2002 and March 2003, complete the following table. If the stockout began prior to April 2002 and continued into this 12 month period, enter March 2003 as stockout start date.

- Note: It may be necessary to use more than one line per product in the table as, for example, there may have been 3 different stockouts of Depo-Provera during this time period.

ENTER THE MAIN REASON FOR THE STOCKOUT. PLEASE USE THE FOLLOWING CODES:

Reason for stockout:

- 1= Higher level facility did not send enough products
- 2= Higher level facility did not send products in time
- 3= Increase in consumption
- 4= Did not request the correct amount
- 5= Did not request products at the correct time
- 6= Insufficient resources (financial, human or transportation, specify
- 7=Other reasons and state the reason in column 9

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[illegible]

## 425. Percent Difference Between Quantity Ordered And Quantity Received:

If this facility does not manage one of the selected products, leave that row blank. See table 427, column 3 to verify which of the 10 products the facility manages.

Method/Brand/ Product	Units	Quantity ordered in last filled order	Date last filled order placed	Quantity received in last filled order/ procurement	Date last filled order received	Comments:
1	2	3	4	5	6	7
Determine test	Test					
Male condom	Piece					
Depo-Provera	Vial					
Cotrimoxazole/ Septrin	400/80 mg tab					
Chloroquine	Adult tab					
Sulphadox. Pyrethamine/ Fansidar	500 mg/25 mg tab					
Ciprofloxacin	500 mg					
Ciprofloxacin	250 mg					
Doxycycline	100 mg tab					
Rifampicin	150 mg tab					

## 425. Laboratory reagents and supplies

Method/Brand/ Product	Units	Quantity ordered in last filled order	Date last filled order placed	Quantity received in last filled order/ procurement	Date last filled order received	Comments:
Full blood count						
Malaria parasites						
Urinalysis						
Blood sugar						
Sputum AFB						

## 425. Storage Conditions table

Items 1-18 should be assessed for all facilities for products that are ready to be issued or distributed to clients. A table should be filled out for each storage area housing only the product categories listed below. Please specify the types of products being assessed in the storage area by circling the category (ies) of products below.

Place a check mark in the appropriate column based on visual inspection of the storage facility, noting any relevant observations in the comments column. *To qualify as “yes,” all products and cartons must meet the criteria for each item.*

Contraceptives      Opportunistic Infection Drugs,      Malarial Drugs,      STI Drugs      TB Medications      ARVs

No	Description	Yes	No	N/A	Comments
1.	Products that are ready for distribution are arranged so that identification labels and expiry dates and/or manufacturing dates are visible.				
2.	Products are stored and organized in a manner accessible for First-Expiry / First-Out (FEFO) counting and general management.				
3.	Cartons and products are in good condition, not crushed due to mishandling. If cartons are open, check if products are not wet or cracked due to heat/radiation (fluorescent lights in the case of condoms)				
4.	The facility makes it a practice to separate damaged and/or expired products from good products and remove them from inventory.				
5.	Products are protected from direct sunlight at all times of the day and during all seasons.				
6.	Cartons and products are protected from water and humidity during all seasons.				
7.	Storage area is visually free from harmful insects and rodents. (Check the storage area for traces of rodents (droppings) or insects).				
8.	Storage area is secured with a lock and key, but accessible during normal working hours, with access limited to authorized personnel.				
9.	Products are stored at the appropriate temperature during all seasons according to product temperature specifications.				
10.	All hazardous waste (e.g., needles, toxic materials) is properly disposed of and non-accessible to non-medical personnel.				
11.	Roof is maintained in good condition to avoid sunlight and water penetration at all times.				
12.	Storeroom is maintained in good condition (e.g. clean, all trash removed, shelves are sturdy, boxes are organized).				
13.	The current space and organization is sufficient for existing products and reasonable expansion (i.e., receipt of expected product deliveries for the foreseeable future).				

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The additional standards below can be applied to any facility large enough to require stacking of multiple boxes.

No.	Description	Yes	No	N/A	Comments
14.	Products are stacked at least 10 cm off the floor.				
15.	Products are stacked at least 30 cm away from the walls and other stacks.				
16.	Products are stacked no more than 2.5 meters high.				
17.	Fire safety equipment is available and accessible (any item identified as being used to promote fire safety should be considered).				
18.	Products are stored separately from insecticides and chemicals.				

### Additional guidelines for specific questions:

**Item 2:** In noting proper product arrangement, the shelf life of the different products should be considered.

**Item 3:** Cartons should be checked to determine whether they are smashed due to mishandling. The conditions of the products inside opened or damaged cartons should also be examined to see if they are wet, cracked open due to heat/radiation (e.g. because of fluorescent lights in the case of condoms) or crushed.

**Item 4:** The discarding of damaged or expired products should be conducted according to the facility's procedures (which may differ from one facility to another). Please specify if procedures exist and note what they are.

**Item 7:** It is important to check the storage area for traces of rodents (droppings) or insects harmful to the products.

**Item 8:** This refers to either a warehouse secured with a lock or to a cabinet with a key in a clinic.

**Item 17:** Fire safety equipment does not have to meet international standards. Any item identified as being used to promote fire safety (e.g. water bucket, sand) should be considered.

## 427. Security For High Value/Controlled Substances

No.	Description	Yes	No	N/A	Comments
1.	Is there a separate, secure storage area for high/value products or controlled substances?				
2.	Is there a doubling-up of staff for picking, packing, and recording of issues for these commodities? (i.e. staff person prepares the order, supervisor verifies?)				
3.	Do both the staff person and supervisor conduct physical inventory of remaining stock prior to shipment of prepared order?				
4.	Is there a doubling-up of staff for unpacking, verification, and recording of receipts for these commodities? (i.e. staff person and supervisor are both present during receipt process?)				
5.	Are there unannounced audits or high value/ controlled substances performed? (Specify frequency and procedure in comments section)				
6.	Describe the security mechanisms in place for protecting high value/controlled substances during transit?				
7.	Describe the security mechanisms in place for dispensing high value/controlled substances to patients?				
8.	Are theft/loss indicators being monitored for these commodities at this site?				
9.	Is staff performance evaluation and compensation (rewards and penalties) tied to theft/loss indicators for these commodities?				
10.	Any other questions?				

COMMENTS OR GENERAL OBSERVATIONS ON COMMODITIES MANAGEMENT:



### **Annex 3**

## **Facility Services and Infrastructure Questionnaire**



## Facility Services and Infrastructure Questionnaire

Questions	VCT	PMTCT	HBC	OI	STI	TB	ART
1. Does this Facility provide this service? If referred, specify where the client/ patient is referred to.	Yes, observed today= 1 Yes, reported today= 2 Yes, not today= 3 <u>No, refer= 4;to</u> No= 102	Yes, observed today= 1 Yes, reported today= 2 Yes, not today= 3 <u>No, refer= 4;to</u> No= 103	Yes, ob today= 1 Yes, rp today= 2 Yes, nt today= 3 <u>No, refer= 4;to</u> No= 107	Yes, ob today= 1 Yes, rp today= 2 Yes, nt today= 3 <u>No, refer= 4;to</u> No= 108	Yes, ob today= 1 Yes, rp today= 2 Yes, nt today= 3 <u>No, refer= 4;to</u> No= 109	1. Diagnosis: Yes, ob today= 1 Yes, rp today= 2 Yes, nt today= 3 <u>No, refer= 4;to</u> No= 110  3. TB Treatment: Yes, ob today= 1 Yes, rp today= 2 Yes, nt today= 3 <u>No, refer= 4;to</u> 4. No= 200	Yes, ob today= 1 Yes, rp today= 2 Yes, nt today= 3 <u>No, refer= 4;to</u> No= 201
2. (a) Is this service offered as a unique service where only client/ patients with HIV-related issues are seen and by specific staff assigned to work with the program, or it is offered as part of the general services?  (b) Are OI services provided as part of (1) in-patient care? (2) HBC (3) If part of HBC how is communication with the patient maintained?	(a) Unique/ HIV/AIDS=1 Integrated with general services= 2 Both= 3 Don't know= 8  (b) see OI and HBC	(a) Unique/ HIV/AIDS=1 Integrated with general services= 2 Both= 3 Don't know= 8  (b) see OI and HBC	(a) Unique/ HIV/AIDS=1 Integrated with general services= 2 Both= 3 Don't know= 8  (b) Pat. Commun.	(a) Unique/ HIV/AIDS=1 Integrated with general services= 2 Both= 3 Don't know= 8	(a) Unique/ HIV/AIDS=1 Integrated with general services= 2 Both= 3 Don't know= 8	Dx: Un. HIV/AIDS= 1 Integrated with general services= 2 Both= 3 Don't Know= 8  Rx: Un. HIV/AIDS= 1 Integrated with general services= 2 Both= 3 Don't Know= 8	(a) Unique/ HIV/AIDS=1 Integrated with general services= 2 Both= 3 Don't know= 8
3. How many days per week is the service available?	Days= None=00 Don't know=98	Days= None=00 Don't know=98	Days= None=00 Don't know=9	Days= None=00 Don't know=9	Days= None=00 Don't know=9	DX Days= None=00 Don't know=9  RX Days= None=00 Don't know=9	Days= None=00 Don't know=9

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Questions	VCT	PMTCT	HBC	OI	STI	TB	ART
4. (a) Is this service provided as outreach  (b) How many days during the month of March 2003 was this service, funded by this facility, actually provided as outreach?	Yes=1 No=2  Days= None=00 Don't know=98	Yes=1 No=2  Days= None=00 Don't know=98	Yes=1 No=2  Days= None=00 Don't know=98	Yes=1 No=2  Days= None=00 Don't know=98	Yes=1 No=2  Days= None=00 Don't know=98	Dx: Yes=1 No=2  Days= None=00 Don't know=98  Rx: Yes=1 No=2  Days= None=00 Don't know=98	Yes=1 No=2  Days= None=00 Don't know=98
5. How many staff are directly involved with client counseling, diagnosis or mangement for this service at one time? Include all staff who have responsibility for any of these activities at any time excluding lab technicians						Dx:    Rx:	
6. Among these staff, how many have received any training related to the service within the last two years (2000-2002) Note approximated dates and source of the training	None=00 Don't know=98  Date:	None=00 Don't know=98  Date:	None=00 Don't know=98  Date:	None=00 Don't know=98  Date:	None=00 Don't know=98  Date:	Dx: None=00 Don't know=98  Date:  Rx: None=00 Don't know=98  Date:	None=00 Don't know=98  Date:
7. Does the facility offer the following program components as part of the service? Circle only when the service is provided and not when the patient/specimen is referred to another facility.	Pre-test counseling= A Testing= B Post-test Coueseling= C Outreach= D	HIV test for pregnant woman= A Counseling on BF= B AZT or NVP = C Prov. Milk formula= D Outreach= 5	Provide home services= 1 Train caretakers= 2 Material support= 3 Community ed. & advocacy= 4 Outreach= 5	Lab Dx= A Chest Xray= B Prescribe medicines= C Counseling for + living= D Outreach= E		Dx:   Rx:	

Questions	VCT	PMTCT	HBC	OI	STI	TB	ART
8. Are there any partner organizations that provide staff or technical support to this facility for the service? Please specify.	Yes= 1 No= 2 Don't know= 8	Yes= 1 No= 2 Don't know= 8	Yes= 1 No= 2 Don't know= 8	Yes= 1 No= 2 Don't know= 8	Yes= 1 No= 2 Don't know= 8	Dx: Yes= 1 No= 2 Don't know= 8  Rx: Yes= 1 No= 2 Don't know= 8	Yes= 1 No= 2 Don't know= 8
9. Do you have any guidelines or protocols indicating how this service should be provided? (If yes, request to see a copy)	Yes, observed= 1 No, not see= 2 None available= 3 Don't know= 8 If yes, specify:	Yes, observed= 1 No, not see= 2 None available= 3 Don't know= 8 If yes, specify:	Yes, observed= 1 No, not see= 2 None available= 3 Don't know= 8 If yes, specify:	Yes, observed= 1 No, not see= 2 None available= 3 Don't know= 8 If yes, specify:	Yes, observed= 1 No, not see= 2 None available= 3 Don't know= 8 If yes, specify:	Dx: Yes, observed= 1 No, not see= 2 None available= 3 Don't know= 8 If yes, specify:  Rx: Yes, observed= 1 No, not see= 2 None available= 3 Don't know= 8 If yes, specify:	Yes, observed= 1 No, not see= 2 None available= 3 Don't know= 8 If yes, specify:
10. Do you have any register or any other record-keeping register where information on clients/patients is recorded? If yes, request to see the register	Yes, observed= 1 No, not see= 2 No= 3	Yes, observed= 1 No, not see= 2 No= 3	Yes, observed= 1 No, not see= 2 No= 3	Yes, observed= 1 No, not see= 2 No= 3	Yes, observed= 1 No, not see= 2 No= 3	Dx: Yes, observed= 1 No, not see= 2 No= 3  Rx: Yes, observed= 1 No, not see= 2 No= 3	Yes, observed= 1 No, not see= 2 No= 3
11. Using report for the month of March 2003, or counting from the register, if report not available indicate how many clients/patients received this service.	None= 000 Don't know= 988	None= 000 Don't know= 988	None= 000 Don't know= 988	None= 000 Don't know= 988	None= 000 Don't know= 988	Dx: None= 000 Don't know= 988  Rx: None= 000 Don't know= 988	None= 000 Don't know= 988



## **Annex 4**

# **Stages of Readiness Assessment Tool: Site Readiness for Antiretroviral Therapy (ART) Introduction**



## Stages of Readiness Assessment Tool: To Evaluate Site Readiness for Antiretroviral Therapy (ART) Introduction

The goal of rating the Stages of Readiness is to develop a set of criteria for selecting ART sites not based on site type, but on capacity, vision, and activities needed for rational introduction and expansion of ART into HIV care.

Six domains of a program are reviewed to assess site readiness: Leadership; Services; Protocols, Management and Evaluation; Experience and Staffing; Lab Capacities, and Drug Management and Procurement. The evaluation of each of these criteria determine which of the five stages a program falls into. The stages rating system can be used for program start-up and expansion within the site to identify steps needed to advance a site along the stages from a Program Mobilization stage (Stage 1) to an Action rating (Stage 4) and, ultimately, Support, Maintenance and Expansion (Stage 5). Examples of technical assistance, training, and resources which may be needed to advance a site to a higher stage are suggested for each rating at the end of the tool.

Leadership					
Leader	Has no identified leadership or commitment at site or in community.	Has some leadership for program at some level at site or in community.	Has leader with vision and some experience managing healthcare-related programs, but needs assistance with starting to design and set up program and protocols.	Has leader with vision and experience managing HIV-related healthcare programs and is engaged in establishing an ART program.	Has strong leader who is spearheading ARV program and has experience or training in managing ARV programs.
	1	2	3	4	5
Model of Care	Has not identified any potential models of care for the ART program.	Have some potential models of care which could be adapted to ART but needs assistance to do so.	Model of care has been chosen or adapted, but lacks details.	A detailed model exists, and operating procedures drafted or being created.	Detailed model of care and operating procedures, both formalized and approved.
	1	2	3	4	5

Total Leadership Score: \_\_\_\_\_

Leadership Score (Total Leadership Score / 2 ): \_\_\_\_\_

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Services					
ART	Few if any staff with outpatient HIV care experience, no ART experience or training.	Have outpatient HIV care experience, but no ART training or experience.	Have some training with ART at certain levels of staff but still inadequate at some levels.	Have some training with ART but limited experience and may require additional training of staff.	Have appropriate training and experience in ART. in all key and most supportive positions.
	1	2	3	4	5
Comprehensive Services*	Have very limited HIV primary care or other important services; either on-site or through linkages.	Access to VCT on-site or by referral, provides HIV primary care or other outpatient HIV medical services on-site; inadequate capacities to expand services without technical assistance.	Has some outpatient HIV medical services on-site or linkages to these services; provides STI treatment and VCT on-site.	Has pMTCT including VCT, Has more extensive HIV outpatient care services provided on-site or by coordinated established linkages including OI and TB treatment. Has either gaps in some support services or linkages to these services or inadequate capacity in areas.	Has VCT on-site, as well as selected essential support services for ART program (adherence, counseling, monitoring and management of toxicities). Has full scope of other services on-site or has coordinated linkages to these services (OI prevention & treatment, STI, pMTCT, TB management, counseling, nutritional counseling, adherence program, access to assistance with concrete support (food, housing), home-based care, family planning, and secondary /positive prevention).
	1	2	3	4	5
Physical Space	Have no space for ART, no confidential space, and no plan for location or expansion.	Extremely limited space overall, no confidential space, and limited plan for expansion.	Have no designated space yet for ART but have plan a plan for it.	Have some space for ART and confidential space, but overall space is limited.	Have defined and adequate clinic space for ART program including access to confidential space.
	1	2	3	4	5
Community Involvement	No community network, involvement or support established or initiated.	Community interest generated through community mobilization for support. Networking initiated including plans to involve PLWHAs	Community meetings underway; community leaders contacted; linkages being established; needs assessment underway; formal or informal input from PLWHAs.	Community networking established between stakeholders in areas of Health admin, govt. community activists, faith-based organizations, etc. Community needs assessment complete; active involvement of PLWHA groups.	Networking has developed into formal referral or community collaboration; has full buy-in of stakeholders including PLWHA's, traditional healers, govt admin, other service organizations and community leaders.
	1	2	3	4	5

\*Comprehensive services important or recommended for ART programs include many aspects of comprehensive HIV care and include:

Critical: ability to screen for eligibility (VCT, clinical, lab), monitoring and management of toxicities and treatment failures, prevention and management of OI's including TB (on-site or by referral), supportive counseling, patient education, adherence support and monitoring, linkages to other needed services (food/nutrition, transportation, etc)

Other services that should be available through linkages or on-site include: family planning, prevention counseling, home-based care.

Total Services Score: \_\_\_\_\_

Services Score (Total Services Score / 4 ): \_\_\_\_\_

Program Protocols/Management/Evaluation					
ART Protocols	May have experience with non-HIV medical care protocols, but no knowledge of or access to draft or National HIV protocols.	Have experience with some HIV-related care protocols but no experience with ARV protocols.	Have access to National protocols but have not been adapted to the site or have not been approved by site management.	Have only working draft guidelines and lacks site specific policies & procedures in some areas.	Have approved protocols for ARV eligibility, screening criteria, regimens, initiation, clinical & lab monitoring & follow-up, adherence, management of side effects, treatment interruption & failure.
	1	2	3	4	5
Management Information Systems (MIS)	No MIS to track patients, no or very basic medical record system.	Basic MIS to track patients but no specific HIV treatment information included. Some elements of medical record system.	Have some elements of MIS but limited capacity for expansion to meet ARV program needs and require improvement in medical record capacity or management.	Have system of following patients, but may have gaps in tracking of patients and medical charting capacity.	Have system in place for tracking patients, medical records and charting for clinical care and labs including specific forms/flow sheets or other processes for ART.
	1	2	3	4	5
Program Monitoring & Evaluation	Have no procedures or plans for program level M&E for any programs.	May have some procedures/ plans for program level M&E for other programs but inadequate for immediate addition of ART to site.	Have HIV-related M&E, some training or access to other M&E resources, but no specific procedures for M&E of ART or quality improvement plan in place.	Have some procedures or plans for program level M&E and quality improvement for ART program but plans need improvement.	Program level M&E includes process & outcome measures of HIV care program including ART, and results are routinely used for program decision making through quality improvement process.
	1	2	3	4	5

Total Protocols/Management Score: \_\_\_\_\_ Protocols/Management Score (Total Protocols/Management Score/3): \_\_\_\_\_

Experience & Staffing					
Experience	Existing staff may have limited outpatient HIV care but no ART experience or training; inadequate human resources for immediate addition of ART to site; no plans for staff expansion or training.	Existing staff with HIV care experience, but no or limited ART experience, and inadequate resources for immediate addition of ART to site, but some plans to expand/train.	Existing staff with HIV care experience, limited training or interest in training for ART. Core staff is present or positions being filled.	Already developed knowledge of or experience with ARVs in treatment and have minimum essential trained staff for prescribing, follow-up and adherence.	Have adequately trained staff with experience in HIV primary care and ART including prescribing, follow-up, adherence support and counseling.
	1	2	3	4	5
Management, Training & Retention	No plan for program staffing needs or management; will require extensive staff training and development.	Has begun to develop staffing plan but need additional expansion of plan for hiring, on-going training and management.	Have staffing plan but with informal plan for hiring process, staff responsibilities, training and/or management system.	Has most staffing plans in place and operational; may require additional hiring or training.	Has adequate staffing plan, including identified staffing responsibilities, on-going training and retention plan, knowledge of staffing needs, and plan to fill gaps in staffing needs.
	1	2	3	4	5

Total Staff Score: \_\_\_\_\_ Staff Score (Total Staff Score / 2 ): \_\_\_\_\_

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Lab Capacity					
Testing Capability	Limited or no access to required labs as defined in minimum WHO/National protocols; no quality assurance mechanism.	Access to required labs as defined in WHO/National protocols is present but not reliable.	Access to required labs for screening and monitoring as defined in WHO/National protocols.	More extensive lab capability, such as LFTs; access to required labs for screening and monitoring excluding CD4s and viral load count; able to do total lymphocyte count.	Have full spectrum of tests as required by site ARV protocol including CD4 count; lab is high quality and has consistent availability.
	1	2	3	4	5
Quality Standards	No quality of standards; no program for equipment maintenance, limited availability of lab supplies.	Poor quality of lab standards; unreliable equipment maintenance program and QA process in place.	Somewhat reliable equipment with somewhat functioning maintenance program and lab supply availability. Lab has some quality standards but compliance is irregular.	Relatively reliable equipment with back-up plan & equipment maintenance program in place. Lab does some internal and external QA. May have occasional breaks in service.	Have internal and external quality assistance, maintenance program, reliable equipment, and continuous availability of reagents and other lab supplies operational.
	1	2	3	4	5

Total Lab Score: \_\_\_\_\_

Lab Score (Total Lab Score / 2 ): \_\_\_\_\_

Drug Management & Procurement					
Supply Chain	Extremely limited supply chain in place, need improvement in multiple areas including ARVs adaptation and creating a QA process for product availability.	Somewhat reliable supply chain in place but needing improvement in one or more areas and needing adaptation to accommodate specific requirements of ARVs; very limited QA process for product availability.	Supply chain in place but may need improvement in one or more areas and need adaptation to accommodate specific requirements of ARVs; have unreliable QA process for product availability.	Have secure supply chain but may have TA needs in inventory management procedures for ARVs; have limited QA process for product availability.	Have secure supply chain from supplier to service site, including appropriate and secure local storage and dispensing and QA system for monitoring product availability to prevent stockouts of ARVs at site.
	1	2	3	4	5
Pharmacy Management	Have no established procedures for ARVs. Do not follow inventory management procedures for other essential drugs.	Have no inventory management procedures for ARVs and limited, unreliable inventory management procedures for other essential drugs.	Have no inventory management procedures for ARVs but have established inventory management procedures for other essential drugs which are clearly implemented.	Have begun developing inventory management procedures for ARVs but incomplete. Have established inventory management procedures for other essential drugs.	Have established inventory management tools and procedures for ARVs including forecasting/ calculating regular re-supply orders, regular stock status reporting, dispensing, and ordering emergency supplies. Have established inventory management procedures for other essential drugs.
	1	2	3	4	5
Financial Resources for ARV and Other Drug Procurement	Have taken no steps towards identifying sources of ARVs. Very limited resources for procurement of drugs for management of HIV-related complications, ARV-related side effects, and other essential drugs.	Have taken no steps towards identifying sources of ARVs. Very limited resources for procurement of drugs for management of HIV-related complications, ARV-related side effects, and other essential drugs.	Have identified potential sources of funding for short-term procurement of ARVs but commitment has not been finalized. Need additional sources of funding to improve availability of other medications for management of HIV-related complications, ARV-related side effects, and other essential drugs.	Have short-term source of funding for initial procurement of ARVs but resources for future funding are insecure. Have adequate supplies of medications for management of HIV-related complications, ARV-related side effects, and other essential drugs.	Have secured source(s) of funding for ARVs required for current and planned patient load for at least the next year and have commitment/plans for follow-up funding. Have adequate supplies of medications for management of HIV-related complications, ARV-related side effects, and other essential drugs.
	1	2	3	4	5

Total Drug Management Score: \_\_\_\_\_

Drug Management Score (Total Drug Management Score / 3 ): \_\_\_\_\_

## Scoring Summary

## What Does the Score Mean?

Bring forward the score from each domain.

Leadership Score

Services Score

Protocols/Management /Evaluation Score

Experience & Staffing Score

Lab Capacity Score

Drug Management & Procurement

**Domain  
Score**

**Lowest Score from  
Within Domain**

The Stages of Readiness Assessment Tool is a qualitative tool that gives a general idea of where an organization falls along the readiness scale of 1 to 5 to initiate an ART program. This tool simply gives a general assessment without emphasizing the importance of one domain over another. An overall score of "5" indicates a program is most ready to go, and a score of "1" indicates that the program needs significant work and planning to be able to start and manage an ART program. It is recommended that a site needs to have at least a score of "3" in each domain to begin ART, and preferably a "4."

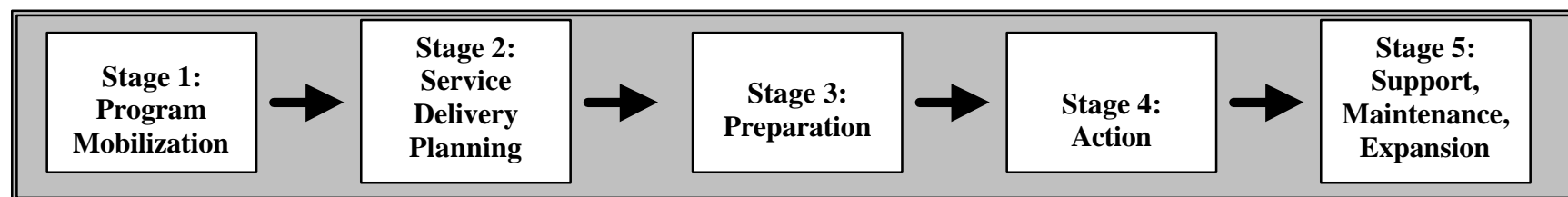
**Overall Program Total**

**Scoring:**

Program Total  
1-8  
9-13  
14-18  
19-24  
25-30

Stage  
1  
2  
3  
4  
5

Each stage is described below with specific activities and recommendations that will move an organization closer to Stage 5, "Support, Maintenance and Expansion."



**Stage 1:  
Program  
Mobilization**

### *Stage 1: Program Mobilization*

These sites are only doing HIV care in the context of the standard outpatient care available at the site but may have OI prevention and screening experience. They are not considering ARVs based on capacity constraints, unwillingness, or other barriers.

Sites at this stage need training and education to expand capacity and knowledge and move to contemplation stage. Other help is needed in technical assistance and support to begin several components including program design and planning, assessment of current capacity, and projecting for staff and other resources required before ARV introduction. These sites might be considered for follow-up of patients on ARVs as a first step, with capacity to initiate ARVs in the future.

Sites may need...

#### *Leadership*

- ... identify or recruit a leader and implement training to develop vision and will to embark on an ARV program.
- ...design a program, including identification of space and model of care.
- ...create links with other sites in-country or the region already providing ARV treatment if possible.

#### Protocols & Management

- ...begin to identify and adopt protocols for eligibility, regimens, initiation, clinical and lab monitoring monitoring and follow-up, adherence, management of side effects, treatment interruption and treatment failure.
- ...TA in development or improvement in MIS system including patient tracking, medical records and charting.
- ...assistance in developing program indicators and appropriate system for M&E of HIV care including ARV treatment which reflects the site's resources and capacity.

#### Services

- ...adopt protocols for ARV use and selection of ARV drug products.
- ...coordinate programs with referral system to ensure follow-up and continuum of care.
- ...identify critical areas which need immediate expansion to reach the next level (ie—VCT, OI treatment, etc.)

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### **Staff**

- ...expand and/or train staff resources in one or more areas to meet at least minimum essential staff for prescribing, follow-up and adherence.

### **Lab**

- ...assistance in developing reliable access to lab services, whether on-site or referral, training, supplies and expansion as required by minimum standards from site protocols.

### **Drug Management & Procurement**

- ...assistance with improving policies and procedures for supply chain management and addressing identified gaps or areas for improvement, including training, systems and pharmacy staff.
- ...assistance in starting to identify and accessing funding sources once leadership is identified and the site model of care has started to be developed.
- ...assistance in development or expansion of QA for monitoring ARV and other product availability.

**Stage 2:  
Service  
Delivery  
Planning**

## *Stage 2: Service Delivery Planning*

These sites have a leader with some vision and interest in ARVs, but with HIV/AIDS capacity and experience limited perhaps to only HIV primary care and possibly pMTCT. They are making efforts to expand services through linkages and staff training.

Sites at this stage need assistance in program design and implementation in a number of areas. These are ideal sites to replicate models proven to be effective in similar settings. These sites might be considered for follow-up of patients on ARVs as a first step, with capacity to initiate ARVs in the future.

Sites may need...

### *Leadership*

- ...assistance with design of program, including defining vision and goals, management plans, identification of space, definition of model, staffing plan and site spectrum of care
- ...linkage with other in-country or regional sites already providing ARV treatment if possible.

### *Protocols & Management*

- ...begin to identify and adopt protocols for eligibility, regimens, initiation, clinical and lab monitoring and follow-up, adherence, management of side effects, treatment interruption and treatment failure.
- ...TA in development or improvement in MIS system including patient tracking, medical records and charting.
- ...assistance in developing program indicators and appropriate system for M&E of HIV care including ARV treatment which reflects the site's resources and capacity.

### *Services*

- ...adopt protocols for ARV use and selection of ARV drug products.
- ...coordinate programs with referral system to ensure follow-up and continuum of care.
- ...identify critical areas which need immediate expansion to reach the next level (ie—VCT, OI treatment, etc.)

### Staff

- ...expansion and/or training of staff resources in one or more areas to meet at least minimum essential staff for prescribing, follow-up and adherence.

### Lab

- ...assistance in maintaining reliable access to lab services, whether on-site or referral, training, supplies and expansion as required by adopted site protocols.

### Drug Management & Procurement

- ...assistance with improving policies and procedures for supply chain management and addressing identified gaps or areas for improvement, including training, systems and pharmacy staff.
- ...assistance in starting to identify and accessing funding sources ARTs.
- ...assistance in development or expansion of QA for monitoring ART and other product availability.

**Stage 3:  
Preparation**
*Stage 3: Preparation (pre-action/on the verge sites)*

Sites with this score have a vision and a leader committed to introduction of ART and are on the verge of beginning to prepare for introduction of ART. They have demonstrated initiative or quality performance in some areas of HIV care (OI, pMTCT), but are missing some components. These sites require more capacity building and funding, but they have potential to start ARV therapy in a matter of three to nine months if resources are available to address needs.

Sites may need...

*Leadership*

- ...better defined goals and vision and be more incorporated into day-to-day activities and future plans.
- ...assistance with design of program, including definition of model, staffing plan and site spectrum of care.

*Protocols & Management*

- ...identify and adopt protocols for eligibility, regimens, initiation, clinical and lab monitoring monitoring and follow-up, adherence, management of side effects, treatment interruption and treatment failure.
- ...TA in development or improvement in MIS system including patient tracking, medical records and charting.
- ...assistance in developing program indicators and appropriate system for M&E of HIV care including ARV treatment which reflects the site's resources and capacity.

*Services*

- ...assistance with identification of space.
- ...expansion at site of scope of services to meet requirements as defined by chosen model of care, and linkages to other organizations to meet other needs.

*Staff*

- ...expansion and/or training of staff resources in one or more areas to meet at least minimum essential staff for prescribing, follow-up and adherence.

*Lab*

- ...assistance in maintaining reliable access to lab services, training and supplies and expansion as required by adopted site protocols.

### Drug Management & Procurement

- ...assistance with improving policies and procedures for supply chain management and addressing identified gaps or areas for improvement.
- ...assistance in identifying and securing resources and ART procurement sources.
- ...assistance in development or expansion of QA for monitoring ART and other product availability.

**Stage 4:  
Action**
*Stage 4: Action*

Sites in this stage are nearly ready or have already started ARV therapy (usually on a smaller scale), but need assistance in one or more critical areas or a number of supportive areas. Efforts are aimed at improving/ensuring rational and safe use of ART and associated services while planning or continuing introduction of ART.

Sites may need...

*Leadership*

- ...better defined goals and vision and be more incorporated into day-to-day activities and future plans.
- ...assistance in estimating needs, problem solving, and program planning.

*Protocols & Management*

- ...assistance in development of formal written protocols for eligibility, regimens, initiation, clinical and lab monitoring and follow-up, adherence, management of side effects, treatment interruption and treatment failure.
- ...assistance in establishing appropriate systems which reflect site resources and capacity.
- ...assistance in developing program indicators and appropriate system for M&E which reflects the site's resources and capacity.

*Services*

- ...a formal plan for initiation or expansion of ARVs at the site may be needed.
- ...assistance in identifying confidential space or other areas.
- ...assistance in expanding scope or capacity of limited number of services through additional resources, hiring or cross-training, or creation of linkages with other organizations to fill gaps.

*Staff*

- ... further training for additional support staff, plans for additional hiring, or assistance with linkages to other organizations to supply other needed services that may be required.

*Lab*

- ...assistance in maintaining reliable access to lab services, training and supplies.

### Drug Management & Procurement

- ...assistance in supply chain logistics to address identified gaps.
- ...assistance in identifying and securing additional resources ARV procurement.
- ...assistance in development or expansion of QA for monitoring ARV and other product availability.

**Stage 5:  
Support,  
Maintenance,  
Expansion***Stage 5: Support, Maintenance and Expansion*

Ideally, sites administering ARVs should meet the criteria for this stage. These sites are already operational and working well, but they may require assistance in maintaining or expanding current efforts. They may also serve as training sites for other organizations in other stages, or may serve as models or may provide technical assistance for replication at other sites locally or elsewhere.

Sites at this stage may need help to meet completely or improve in some of these criteria, but most efforts will be maintaining or expanding capacity, on-going education (patients and providers), and QA.



## **Annex 5**

# **List of Persons Contacted**



## List of Persons Contacted

### Accra:

Mr. Parfait Edah	Resident Advisor, JSI/Deliver
Mr. Peter Wondergem	USAID
Mr. Samuel Boateng	Director, SSDM
Ms. Martha Ghansah-Lutterodt	Drug Policy Unit, GHS/MOH
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Mr. Mbuba Mbungu	Senior Procurement Specialist, The World Bank/Ghana
Prof. Sakyi Awuku Amoah	Director-General, Ghana AIDS Commission
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Dr. Alex Asamoah-Adu	Director, Public Health Reference Laboratory
Ms. Veronica Bekoe	Chief Biologist & Deputy Director, Public Health Reference Laboratory
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Dr. William Ampofu	Research Fellow, Noguchi Memorial Institute for Medical Research
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Dr. Augustt Addama	Chief of Medicine, AGC Hospital
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Sister Susie Mensah	AGC Hospital
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Dr. Frank Nyonator	Director, Policy Planning Monitoring & Evaluation, GHS
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Mr. Robert Adinyira	Medical Lab Technologist, Nyaho Clinic
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Dr. Dalmeida	Physician, Nyaho Clinic
Mr. Peter Hiadzi	Records Officer, Nyaho Clinic
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Dr. Joycelyn Afful	Medical Officer, Holy Trinity Hospital
Mr. James Frimpong	Pharmacist, Holy Trinity Hospital
Mr. Vivian Kwofie	Head, Medical Lab Technologist, Holy Trinity Hospital
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Mrs. Evelyn Quaye

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Mr. Joseph Sacky

Sister Margaret Mary

Mr. Abraham Tetteh

John Boameyeh Yanney

Samuel Appiah

John Nartey Baah

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Dispenser

Dispenser

Laboratory Technician i/c

Laboratory Technician

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Pharmacist

Senior Pharmacist

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Mr. Kojo Nkwantabisa

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Director, Microbiology Laboratory

Pharmacist

Director, OB/GYN

Chair, HIV Committee

Pediatrician

Department of Medicine/Oncology

Deputy Director Pharmacy Services

Sr. Pharmacist, Special Pharmacy Unit/OPD

Sr. Stores Officer

**USA:**

Ms. Mary Lyn Field-Nguer

Mr. Rich Feeley

Associate Director, Start Program, FHI, USA (prior to travel to Ghana)

Commercial Marketing Services/Boston University (by phone)

## **Annex 6**

# **Antiretroviral Drugs Registered by the Food and Drug Board in Ghana**



## Antiretroviral Drugs Registered by the Food and Drug Board in Ghana

No.	Name Of Product	Active Ingredient	Manufacturer	Local Agent
1	Combivir Tablets	Lamivudine 150mg,Zidovudine 300mg	Glaxowellcome, South Africa	Glaxowellcome (GH) Office
2	Fortovase Capsules	Saquinnavir 200mg	Hoffnan-La Roche, Switzerland	Samvide Ltd, Accra
3	Viracept Tablets	Nelfinavir 250mg	Hoffman-La Roche,Switzerland	Samvide Ltd, Accra
4	Zidovir 100 Capsules	Zidovudine 100mg	Cipla Ltd,India	Healthcare Services Ltd
5	Stavir 40 Capsules	Stavudine 40mg	Cipla Ltd,India	Healthcare Services Ltd
6	Stavir 30 Capsules	Stavudine 30mg	Cipla Ltd,India	Healthcare Services Ltd
7	Lamivir 150 Tablets	Lamivudine 150mg	Cipla Ltd,India	Healthcare Services Ltd
8	Viramune Tablets	Nevirapine 200mg	Boehringer Ingelheim, South Africa	
9	Viramune Oral suspension	Nevirapine 50mg/5m1	Boehringer Ingelheim, South Africa	
10	Duovir Tablets	Lamivudine 150mg, Zidovudine 300mg	Cipla Ltd, India	Healthcare Services Ltd
11	Cirixivan Capsules	Indinavir 200mg	Merck Sharp & Dohme, France	Reiss & Co Ltd
12	Cirixivan Capsules	Indinavir 400mg	Merck Sharp & Dohme, France	Reiss & Co Ltd
13	Stocrin Tablets	Efavirenz 200mg	Merck Sharp & Dohme, France	Reiss & Co Ltd
14	Retrovir 100 capsules	Zidovudine 100mg	Glaxowellcome,U.K	Gokals Ltd
15	Retrovir 250 capsules	Zidovudine 250mg	Glaxowellcome,U.K	Gokals Ltd
16	Retrovir 300 Tablets	Zidovudine 300mg	Glaxowellcome,U.K	Gokals Ltd
17	Ziagen Oral Solution	Abacavir 20mg/ml	Glaxowellcome,U.K	Gokals Ltd
18	Ziagen Tablets	Abacavir 300mg	Glaxowellcome,U.K	Gokals Ltd
19	Epivir Tablets	Lamivudine 150mg	Glaxowellcome,U.K	Gokals Ltd
20	Epivir Oral Solution	Lamivudine 10mg/ml	Glaxowellcome,U.K	Gokals Ltd



## **Annex 7**

# **Antiretroviral Therapy Treatment Protocols**



# Antiretroviral Therapy Treatment Protocols

One drug/combination is chosen from group A and one from group B

	Column A	Column B
FIRST LINE DRUGS	Efavirenz	Stavudine + Lamivudine
	Nevirapine* (as single dose for Prevention for mother to child transmission)	Stavudine + Didanosine
		Zidovudine + Lamivudine
		Zidovudine + Didanosine
SECOND LINE DRUGS**	Nevirapine (as part of triple therapy)	
	Indinavir	
	Nelfinavir	

\*Nevirapine single dose therapy is being used for the prevention of mother to child transmission program alone.

\*\* Second line drugs may be used in individuals who fit the criteria for change of therapy. Preferably all ARVs should be changed.



## **Annex 8**

# **HIV Tests and Testing Protocol In Ghana**



# HIV Tests And Testing Protocol In Ghana

## Voluntary Testing and Counseling

### Central and Regional Level Facilities

1 <sup>st</sup> test	Determine
2 <sup>nd</sup> test	HIVSpot to be replaced with Rapitest
Tiebreaker	Innotest at Regional Lab to be replaced with Vironostika

### Peripheral Facilities

1 <sup>st</sup> test	Determine
2 <sup>nd</sup> test	HIVSpot to be replaced with Rapitest
Tiebreaker	Innotest at Regional Lab to be replaced with Vironostika

## Clinical Diagnosis

### Central and Regional Level Facilities

1 <sup>st</sup> test	Innotest to be replaced with Vironostika
2 <sup>nd</sup> test	Determine
Tiebreaker	Innolia at PHRL

### Peripheral Facilities

1 <sup>st</sup> test	Determine
2 <sup>nd</sup> test	Rapitest
Tiebreaker	Innotest at Regional Lab to be replaced with Vironostika

## Surveillance

### Central and Regional Level Facilities

1 <sup>st</sup> test	Innotest to be replaced with Vironostika
If reactive	Innolia at PHRL

### Peripheral Facilities

1 <sup>st</sup> test	Determine
If reactive	Innolia at PHRL

## Blood Safety – One test used

### Central and Regional Level Facilities

1 <sup>st</sup> test	Innotest to be replaced with Vironostika
If reactive	Discard blood
If negative	Use blood

### Peripheral Facilities

1 <sup>st</sup> test	Determine
If reactive	Discard blood
If negative	Use blood



# References

- Amoa, Prof. S. A. "Overview of Multi-Sectoral Response in Ghana." Ghana: Ghana AIDS Commission. Country Coordinating Mechanism, Government of Ghana. 5 March 2002. *Proposal to the Global Fund to Fight AIDS, Tuberculosis and Malaria*. Accra: Government of Ghana.
- Family Health International (FHI). June 2002. *Quality Assurance Measures for Voluntary Counseling and Testing Services*. Arlington, Va.: FHI.
- FHI Start Program. *Monitoring and Evaluation Forms*. Arlington, Va.: Family Health International.
- Ghana AIDS Commission. February 2003. *8<sup>th</sup> Draft National Monitoring and Evaluation Framework for HIV/AIDS*. N.p.: Ghana AIDS Commission.
- Ghana AIDS Commission. 2001. *Annual Report: Report for the year Ended 31<sup>st</sup> December 2001*. N.p.: Ghana AIDS Commission.
- Ghana AIDS Commission. March 2003. *National Guidelines for the Development and Implementation of HIV Voluntary Counseling and Testing in Ghana*. Draft. N.p.: Ghana AIDS Commission.
- John Snow, Inc./DELIVER. February 2003. *Ghana Country Strategic and Evaluation Plan*. Arlington, Va.: DELIVER, for the U. S. Agency for International Development.
- John Snow, Inc./DELIVER. December 2002. *Logistics System Assessment Tool Results*. Arlington, Va.: DELIVER, for the U. S. Agency for International Development.
- Ministry of Health/Ghana Health Service (MOH/GHS). September 2002. *Guidelines for Antiretroviral Therapy in Ghana*. N.p.: MOH/GHS.
- Ministry of Health/Ghana Health Service (MOH/GHS). October 2002 (Reviewed April 2003). *HIV/AIDS Strategic Plan 2002-2006*. N.p.: MOH/GHS.
- Ministry of Health/Ghana Health Service (MOH/GHS). 5 March 2002. *Proposal to the Global Fund to Fight AIDS, Tuberculosis and Malaria Interim Secretariat*. Ghana: MOH/GHS.
- National AIDS Control Programme, Epidemiology Division, Ministry of Health (MOH), Ghana. February 2000. *AIDS: A Manual for Training Counselors*. Ghana: MOH.
- National AIDS/STI Control Programme, Disease Control Unit, Ministry of Health/Ghana Health Service (MOH/GHS). September 2002. *Guidelines for Management of Opportunistic Infections and Other Related HIV Diseases*. Ghana: MOH/GHS.
- National AIDS Control Programme. May 2002. *HIV Sentinel Surveillance 2001*. N.p.
- National AIDS Control Programme. N.d. Memo: *ART Situation and Future Requirements for Ghana*. N.p.
- National AIDS/STI Control Programme, Disease Control Unit, Ministry of Health. December 2001. *HIV/AIDS in Ghana: Background, Projections, Impacts, Interventions and Policy*. Ghana: N.p.
- National AIDS/STI Control Programme, Ministry of Health/Ghana Health Service (MOH/GHS). September 2002. *Sexually Transmitted Infections: Guidelines for Management*. Ghana: MOH/GHS.
- Noguera, Marilyn, David Alt, Dr. Lisa Hirschhorn, Dr. Chiedza Maponga, Dr. Patrick Osewe, and Dr. Amos Sam-Abbenyi. 2003. *Zimbabwe: Antiretroviral Therapy Program—Issues and Opportunities for Initiation and Expansion*. Arlington, Va.: DELIVER/John Snow, Inc., for the U.S. Agency for International Development.